

FEDERAL REGISTER

Vol. 83 Thursday,

No. 139 July 19, 2018

Pages 34021-34468

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, 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, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

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

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

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

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com*.

The annual subscription price for the Federal Register paper edition is \$860 plus postage, or \$929, for a combined Federal Register, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the Federal Register including the Federal Register Index and LSA is \$330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily Federal Register, including postage, is based on the number of pages: \$11 for an issue containing less than 200 pages; \$22 for an issue containing 200 to 400 pages; and \$33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for \$3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see bookstore.gpo.gov.

There are no restrictions on the republication of material appearing in the $\bf Federal\ Register.$

How To Cite This Publication: Use the volume number and the page number. Example: 83 FR 12345.

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche 202–512–1800
Assistance with public subscriptions 202–512–1806

General online information 202–512–1530; 1–888–293–6498

Single copies/back copies:

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

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

 Email
 FRSubscriptions@nara.gov

 Phone
 202-741-6000



Contents

Federal Register

Vol. 83, No. 139

Thursday, July 19, 2018

Agency for International Development

NOTICES

Meetings:

Board for International Food and Agricultural Development, 34098

Agency for Toxic Substances and Disease Registry

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 34135–34137

Agriculture Department

See Commodity Credit Corporation See Food and Nutrition Service See Food Safety and Inspection Service

Census Bureau

NOTICES

Users on 2020 Census Data Products, 34111-34112

Centers for Medicare & Medicaid Services PROPOSED RULES

Medicare Program:

End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Amounts, etc., 34304-34415

Civil Rights Commission

NOTICES

Nevada State Advisory Committee, 34110-34111

Coast Guard

RULES

Drawbridge Operations:

Willamette River at Portland, OR, 34041

Regulated Navigation Areas:

Chicago Sanitary and Ship Canal, Romeoville, IL, 34042-34046

Safety Zones:

Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez; Valdez, AK; Correction, 34042 Southern California Annual Firework Events for the San Diego Captain of the Port Zone, 34041-34042 Swim Event in Captain of the Port New York Zone,

PROPOSED RULES

Safety Zones:

Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA, 34092-34094

Commerce Department

34046 - 34047

See Census Bureau

See International Trade Administration

See National Oceanic and Atmospheric Administration

Commodity Credit Corporation

NOTICES

Funding Availability:

Conservation Reserve Program Forest Inventory Analysis Pilot, 34098-34100

Commodity Futures Trading Commission

NOTICES

Privacy Act; Systems of Records, 34123-34126

Education Department

RULES

Student Assistance General Provisions, Federal Perkins Loan Program, Federal Family Education Loan Program, William D. Ford Federal Direct Loan Program, and Teacher Education Assistance for College and Higher Education Grant Program; Corrections, 34047– 34049

NOTICES

Privacy Act; Matching Program, 34126-34127

Energy Department

See Federal Energy Regulatory Commission

Environmental Protection Agency

RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Michigan; Revisions to Part 9 Miscellaneous Rules, 34050-34051

PROPOSED RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Oregon; Interstate Transport Requirements for the 2012 PM_{2.5} NAAQS, 34094–34096

NOTICES

Pesticide Product Registrations; Applications:

New Active Ingredients, 34128-34131

New Uses, 34131-34132

Export-Import Bank

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 34132-34133

Federal Aviation Administration RULES

Airworthiness Directives:

Airbus Airplanes, 34034–34039

Airbus Helicopters, 34029-34031

ATR-GIE Avions de Transport Regional Airplanes, 34031-34034

Settlement Policy for Commercial Pilots In Drug and

Alcohol Testing Cases, 34040-34041 Special Conditions:

Cranfield Aerospace Limited, Textron Aviation Inc. Model 525-Series Airplanes; Tamarack Load Alleviation System and Cranfield Winglets-Interaction of Systems and Structures, 34022-34028

PROPOSED RULES

Airworthiness Directives:

Bell Helicopter Textron Canada Limited Helicopters, 34074-34076

Leonardo S.p.A. Helicopters, 34072–34074 Pratt and Whitney Division Turbofan Engines, 34070–34072

Federal Communications Commission PROPOSED RULES

FM Translator Interference:

Extension of Time to File Comments and Reply Comments, 34096–34097

Federal Emergency Management Agency

RULES

Suspension of Community Eligibility, 34052-34053 **NOTICES**

Flood Hazard Determinations; Changes, 34147–34152 Flood Hazard Determinations; Proposals, 34146–34147, 34153–34154

Major Disaster and Related Determinations:

Maryland, 34150

Oklahoma, 34145

Major Disaster Declarations:

Hawaii; Amendment No. 1, 34145, 34150

Federal Energy Regulatory Commission NOTICES

Filings:

Oncor Electric Delivery Company, LLC, 34127-34128

Federal Highway Administration

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 34282–34283 Federal Agency Actions: California; Proposed Highway, 34281–34283

Federal Maritime Commission

NOTICES

Agreements Filed, 34133

Federal Motor Carrier Safety Administration

NOTICES

Meetings; Sunshine Act, 34283

Federal Railroad Administration

Funding Opportunities:

Consolidated Rail Infrastructure and Safety Improvements, 34283–34295

Federal Transit Administration

RULES

Public Transportation Agency Safety Plan, 34418–34468 Public Transportation Safety Certification Training Program, 34053–34069

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Anti-Money Laundering Programs for Insurance Companies and Non-Bank Residential Mortgage Lenders and Originators, 34298–34299

Bank Secrecy Act Regulations Requiring Money Services Businesses to Report Suspicious Activity, 34298

Bank Secrecy Act Suspicious Activity Reporting Non-Bank Requirement for Residential Mortgage Lenders and Originators, 34300–34301

Registration of Money Services Business, Regulation and FinCEN Form, 34299–34300

Fish and Wildlife Service

NOTICES

Draft Long-Range Transportation Plans for Lands in Regions 2, 6, and 8, 34154–34155

Endangered and Threatened Species:

Draft Recovery Plan for the Southern California Distinct Population Segment of the Mountain Yellow-legged Frog, 34155–34156

Food and Drug Administration

PROPOSED RULES

Food Additive Petitions (Animal Use):

Humic Product Trade Assn.; Withdrawal, 34076

Guidance:

E17 General Principles for Planning and Design of Multiregional Clinical Trials; International Council for Harmonisation, 34139–34140

Field Alert Report Submission: Questions and Answers, 34142–34143

Labeling for Biosimilar Products, 34141–34142 Use of Electronic Health Record Data in Clinical Investigations, 34137–34138

Priority Review Vouchers:

Rare Pediatric Disease Product, 34139

Food and Nutrition Service

NOTICES

Child and Adult Care Food Program:

National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period July 1, 2018 through June 30, 2019, 34108–34110

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates, 34105–34108

Food Safety and Inspection Service NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Consumer Research on the Safe Handling Instructions
Label for Raw and Partially Cooked Meat and Poultry
Products and Labeling Statements for Ready-to-Eat
and Not-Ready-to-Eat Products, 34101–34103
Food Defense Vulnerability Questionnaire, 34104–34105

Foreign Assets Control Office

NOTICES

Blocking or Unblocking of Persons and Properties, 34301–34302

General Services Administration

NOTICES

Federal Travel Regulations:

Relocation Allowances—Waiver of Certain Provisions of the FTR Chapter 302 for Official Relocation Travel to Locations in the U.S. Virgin Islands and Commonwealth of Puerto Rico Impacted by Hurricanes Irma and Maria, 34133–34134

Government Ethics Office

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:

Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, 34134–34135

Gulf Coast Ecosystem Restoration Council

Proposed Subaward under a Council-Selected Restoration Component Award, 34135

Health and Human Services Department

See Agency for Toxic Substances and Disease Registry

See Centers for Medicare & Medicaid Services

See Food and Drug Administration

See National Institutes of Health

See Substance Abuse and Mental Health Services
Administration

Homeland Security Department

See Coast Guard

See Federal Emergency Management Agency

Interior Department

See Fish and Wildlife Service

See Land Management Bureau

See National Park Service

NOTICES

Privacy Act; Systems of Records, 34156-34161

International Trade Administration

NOTICES

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Certain Carbon and Alloy Steel Cut-to-Length Plate from the People's Republic of China, 34115–34116

Welded Line Pipe from the Republic of Turkey, 34113–34114

Corporation for Travel Promotion Board of Directors, 34112–34113

Determinations of Sales at Less than Fair Value: Circular Welded Carbon-Quality Steel Pipe From the United Arab Emirates, 34114–34115

International Trade Commission NOTICES

Investigations; Determinations, Modifications, and Rulings, etc.:

Fine Denier Polyester Staple Fiber from China, India, Korea, and Taiwan, 34163–34164

Judicial Conference of the United States NOTICES

Meetings:

Advisory Committee on Rules of Criminal Procedure, 34164

Justice Department

See Parole Commission

Labor Department

See Occupational Safety and Health Administration

Land Management Bureau

NOTICES

License Applications:

Coal Exploration; WYW186226, Wyoming; Invitation to Participate, 34161–34162

Meetings:

Alaska Resource Advisory Council, 34163

John Day—Snake Resource Advisory Council, 34162—34163

Requests for Nominations:

National Petroleum Reserve in Alaska 2018 Oil and Gas Lease Sale, 34161

Management and Budget Office

NOTICES

Senior Executive Service Performance Review Board Membership, 34164

Maritime Administration

NOTICES

Requests for Administrative Waivers of the Coastwise Trade Laws:

Vessel ACQUA BLU, 34295-34296

Vessel MONTRACHET, 34296-34297

Vessel VENOM, 34296

National Archives and Records Administration NOTICES

Senior Executive Service Performance Review Board; Members, 34164–34165

National Foundation on the Arts and the Humanities NOTICES

Meetings:

Arts and Artifacts Indemnity Panel Advisory Committee, 34165

National Institutes of Health

NOTICES

Meetings:

Eunice Kennedy Shriver National Institute of Child Health and Human Development, 34144 National Institute of Neurological Disorders and Stroke, 34144

National Institute on Drug Abuse, 34143-34144

National Oceanic and Atmospheric Administration NOTICES

Fisheries of the Exclusive Economic Zone off Alaska: Bering Sea and Aleutian Islands Crab Rationalization Cost Recovery Program, 34119–34120

Meetings:

Coral Reef Conservation Program, 34121 Gulf of Mexico Fishery Management Council, 34117– 34118, 34120–34121

New England Fishery Management Council, 34117 Pacific Fishery Management Council, 34118–34119 Sanctuary System Business Advisory Council, 34120 South Atlantic Fishery Management Council, 34121–34122

Permits:

Marine Mammals and Endangered Species, 34116 Marine Mammals; File No. 21329, 34118 Requests for Nominations:

Advisory Committee on Commercial Remote Sensing, 34122–34123

National Park Service

PROPOSED RULES

Alaska; Hunting and Trapping in National Preserves, 34094

Occupational Safety and Health Administration PROPOSED BULES

Cranes and Derricks in Construction: Railroad Roadway Work, 34076–34092

Parole Commission

NOTICES

Meetings; Sunshine Act, 34164

Pipeline and Hazardous Materials Safety Administration NOTICES

Meetings:

Pipeline Research and Development Forum, 34297-34298

Securities and Exchange Commission NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 34165, 34179–34182, 34190–34192, 34276–34277, 34279–34281

Self-Regulatory Organizations; Proposed Rule Changes: Chicago Stock Exchange, Inc., 34182–34190 Fixed Income Clearing Corp., 34193–34227 Investors Exchange, LLC, 34277–34279 National Securities Clearing Corp., 34166–34179, 34227–

The Depository Trust Co., 34246-34276

Small Business Administration

RULES

504 Loan Program Rural Initiative:

Waiver of Limitation on Lending Authority, 34021–34022

State Department

NOTICES

Culturally Significant Objects Imported for Exhibition: Determinations: Titian's Lady in White: A Renaissance Portrait Revealed Exhibition, 34281

Substance Abuse and Mental Health Services Administration

NOTICES

Meetings:

Center for Substance Abuse Prevention, 34144–34145

Surface Transportation Board NOTICES

Acquisition and Operation Exemptions: Atlantic and Western Railway, LP; CSX Transportation, Inc., 34281

Transportation Department

See Federal Aviation Administration

See Federal Highway Administration

See Federal Motor Carrier Safety Administration

See Federal Railroad Administration

See Federal Transit Administration

See Maritime Administration

See Pipeline and Hazardous Materials Safety Administration

Treasury Department

See Financial Crimes Enforcement Network See Foreign Assets Control Office

Veterans Affairs Department

NOTICES

Requests for Nominations:

Advisory Committee on Women Veterans, 34302

Separate Parts In This Issue

Part II

Health and Human Services Department, Centers for Medicare & Medicaid Services, 34304–34415

Part III

Transportation Department, Federal Transit Administration, 34418–34468

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 electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

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.

| 13 CFR | |
|--------------------------|-----------------------|
| 120 | 34021 |
| 14 CFR 23 | 34022 |
| 39 (3 documents) | 34029, |
| 61 | 4031, 34034 |
| 67 | 34040 |
| 91 120 | |
| Proposed Rules: | |
| 39 (3 documents) | 34070, 4072. 34074 |
| 21 CFR | 4072, 04074 |
| Proposed Rules: | |
| 573 | 34076 |
| 29 CFR | |
| Proposed Rules: | 34076 |
| 33 CFR | |
| 117 165 (4 documents) | 34041 |
| 3 | 4042, 34046 |
| Proposed Rules: | 34092 |
| 34 CFR | 07002 |
| 685 | 34047 |
| 36 CFR | |
| Proposed Rules: | 34094 |
| 40 CFR | |
| 52 | 34050 |
| Proposed Rules: 52 | 34094 |
| 42 CFR | |
| Proposed Rules: | |
| 413 414 | 34304 |
| 44 CFR | |
| 64 | 34052 |
| 47 CFR | |
| Proposed Rules: 74 | 34096 |
| 49 CFR | |
| 672 673 | |
| o, o | |

Rules and Regulations

Federal Register

Vol. 83, No. 139

Thursday, July 19, 2018

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.

SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

504 Loan Program Rural Initiative— Waiver of Limitation on Lending Authority

AGENCY: U.S. Small Business Administration.

ACTION: Notification of 504 Loan Program Rural Initiative Pilot Program and impact on regulatory provisions.

SUMMARY: The U.S. Small Business Administration (SBA) announces the 504 Loan Program Rural Initiative Pilot Program (504 Rural Pilot), as described in this document, and its impact on Agency regulations. The 504 Rural Pilot waives the restrictions on the authority of Certified Development Companies (CDCs) to make 504 loans outside their Area of Operations to allow each CDC to make loans for 504 Projects with an address located in any rural county if the 504 Project is located in the same SBA Region in which the CDC is incorporated. This pilot will provide rural small businesses with increased opportunities to access capital and will further the statutory public policy goal of the 504 Loan Program to achieve rural development impact.

DATES: The 504 Rural Pilot, including the waiver of the restrictions in 13 CFR 120.839 on CDCs' authority to make loans outside their Area of Operations, will be available from July 19, 2018, through July 20, 2020.

FOR FURTHER INFORMATION CONTACT:

Linda Reilly, Chief, 504 Program
Branch, Office of Financial Assistance,
U.S. Small Business Administration,
409 Third Street SW, Washington, DC
20416; Telephone (202) 205–9949; email
address: linda.reilly@sba.gov.

SUPPLEMENTARY INFORMATION: The 504 Loan Program is a financing tool authorized under title V of the Small Business Investment Act of 1958 (SBIAct) to provide small businesses with long-term, fixed-rate financing to

help acquire major fixed assets for expansion or modernization. A Certified Development Company (CDC) is typically a private, nonprofit corporation set up to contribute to the economic development of its community. CDCs work with SBA and private sector lenders to provide financing to small businesses under the 504 Loan Program. In general, a 504 project includes: A loan obtained from a private sector lender with a senior lien covering at least 50 percent of the project cost; a loan obtained from a CDC with a junior lien covering up to 40 percent of the project cost (backed by a 100 percent SBA-guaranteed debenture); and a contribution from the Borrower of at least 10 percent of the project cost.

Under 13 CFR 120.821, a CDC is required to operate only within its designated Area of Operations approved by SBA, except as provided in 13 CFR 120.839. Each CDC's approved Area of Operations includes the entire State in which it is incorporated (see 13 CFR 120.810(b)). A CDC also may apply and be approved to expand its Area of Operations into a Local Economic Area under 13 CFR 120.835(b) or by becoming a Multi-State CDC under 13 CFR 120.835(c). Under 13 CFR 120.839, a CDC may submit a request to the Sacramento Loan Processing Center (SLPC) to make a 504 loan for a 504 Project outside its Area of Operations. In such case, the CDC must demonstrate that it can adequately fulfill its 504 program responsibilities for the 504 loan, including proper servicing, and have satisfactory SBA performance, as determined by ŠBA in its discretion. The SLPC may approve the application if, in addition to other requirements, (1) the CDC has previously assisted the business to obtain a 504 loan, (2) the existing CDC or CDCs serving the area agree to permit the applicant CDC to make the 504 loan, or (3) there is no CDC within the Area of Operations in which the 504 Project is located.

One of the statutory public policy goals of the 504 Loan Program is to achieve rural development. See section 501(d)(3)(D) of the SBIAct. Since 2013, a significant number of rural CDCs have voluntarily decertified, while SBA has approved only two new rural CDCs. SBA has historically found that increasing the CDC operating service area results in more 504 loan activity. However, in accordance with 13 CFR

120.835, CDCs are only permitted to expand their Area of Operations by requesting Local Economic Area expansion or Multi-State authority. This authority limits CDC expansion to areas and States contiguous to a CDC's Area of Operations.

In order to address this issue and increase lending in rural areas, SBA has developed the 504 Rural Pilot. This Pilot allows CDCs to make loans for 504 Projects with an address located in any county classified as "rural" by the U.S. Census Bureau if the 504 Project is located in the same SBA Region in which the CDC is incorporated. SBA expects that the expansion of a CDC's authority to process rural loans anywhere within their SBA-defined Region will result in increased lending and economic growth in rural markets.

Specifically, for purposes of the 504 Rural Pilot, SBA is *waiving* the following requirements in 13 CFR 120.839 (*i.e.*, these requirements will *not* apply to 504 Rural Pilot loans):

(1) The CDC must apply to the Sacramento Loan Processing Center in order to make the 504 loan for the 504 Project outside of its Area of Operation;

(2) The CDC must demonstrate that it can adequately fulfill its 504 program responsibilities for the 504 loan;

(3) SBA must determine that the CDC has satisfactory SBA performance; and

(4) The CDC must have previously assisted the business to obtain a 504 loan, the existing CDC or CDCs serving the area agree to permit the outside CDC to make the 504 loan, or there is no CDC within the Area of Operations in which the 504 Project is located.

Under the 504 Rural Pilot, a CDC may make a 504 loan for a 504 Project located outside the CDC's Area of Operations only if the 504 Project address is located in a rural county that is in the same SBA Region in which the CDC is incorporated. For purposes of the 504 Rural Pilot, rural counties are those counties classified as "mostly rural" or "completely rural" by the U.S. Census Bureau in its most recent decennial census report, and are identified in the County Classification Lookup Table that can be downloaded at www.sba.gov/about-sba/sba*initiatives/sba-rural-lending-initiative* or on the Welcome Screen for the Capital Access Financial System (CAFS). (CDCs must use the U.S. Census Bureau table for purposes of identifying rural

counties for the 504 Rural Pilot, which may not be the same as the rural areas identified by the U.S. Department of Agriculture.) SBA Regions are defined as follows:

- Region I: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont
- Region II: New York, New Jersey, Puerto Rico, and The U.S. Virgin Islands
- Region III: Delaware, Maryland, Pennsylvania, Virginia, Washington, DC, and West Virginia
- Region IV: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee
- Region V: Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin
- Region VI: Arkansas, Louisiana, New Mexico, Oklahoma, and Texas
- Region VII: Iowa, Kansas, Missouri, and Nebraska
- Region VIII: Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming
- Region IX: Arizona, California, Guam, Hawaii, and Nevada
- Region X: Alaska, Idaho, Oregon, and Washington.

In making, closing, servicing, or liquidating a 504 Rural Pilot loan, CDCs must follow all other Loan Program Requirements under the 504 Loan Program, except that 504 Rural Pilot loans cannot be made using the CDC's delegated authority (i.e., PCLP or ALP authority). Although, as described above, CDCs will not be required "to demonstrate" that they can adequately fulfill their 504 program responsibilities for each 504 Rural Pilot loan before making the loan, CDCs will still be expected to fulfill all such program responsibilities with respect to these loans.

Unlike a Multi-State CDC, a CDC making a loan under this pilot will not be required to establish a separate loan committee to cover the State in which the rural 504 Project is located. In addition, the CDC must advise the local District Counsel where the 504 Project is located which Designated Attorney, or other attorney, will be closing the loan. (The attorney must be licensed in the State where the loan is being made.) CDCs should note that the CDC may not close the loan as an expedited loan unless the attorney is a Designated Attorney licensed to practice in the State where the 504 Project is located. The CDC is responsible for notifying the SLPC that a 504 loan application is being submitted under the 504 Rural Pilot.

SBA's waiver of the above requirements is authorized by 13 CFR

120.3 of its regulations, which provides that the SBA Administrator may suspend, modify or waive rules for a limited period of time to test new programs or ideas. The 504 Rural Pilot will be available for a two year period beginning today.

SBA will limit the number of loans made under the 504 Rural Pilot to not more than ten percent of the total number of 504 loans guaranteed by SBA in any fiscal year. While SBA does not expect the number of 504 Rural Pilot loans to reach that limit, SBA will provide public notice of the need to suspend lending under the 504 Rural Pilot for the remainder of the fiscal year if SBA determines that the number of pilot loans is approaching the limit.

SBA will be using the following criteria to evaluate the 504 Rural Pilot to determine how well it is achieving its objectives and other aspects of performance: (1) The measurable objectives to be achieved through the 504 Rural Pilot, including the number of small business concerns served, and the delinquency and default rates on the 504 Rural Pilot loans compared to regular 504 loans; (2) the number of CDCs that participate in the 504 Rural Pilot and their performance in making and servicing 504 Rural Pilot loans; and (3) the costs and standards of performance which, in order to be acceptable, must not impact the overall subsidy rate for the 504 Loan Program. For data collections to evaluate the effectiveness of this pilot, SBA will use ETran, SBA's electronic system for loan submission and servicing.

Authority: 13 CFR 120.3.

Dated: July 6, 2018. Linda E. McMahon,

Administrator.

[FR Doc. 2018-15312 Filed 7-18-18; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. FAA-2016-9409; Special Conditions No. 23-279A-SC]

Special Conditions: Cranfield Aerospace Limited, Textron Aviation Inc. Model 525-Series Airplanes; Tamarack Load Alleviation System and Cranfield Winglets—Interaction of Systems and Structures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Amended final special conditions; request for comments.

SUMMARY: These amended special conditions are issued for the Textron Aviation Inc. Model 525-series airplanes. These airplanes—as modified by Cranfield Aerospace Limited—will have a novel or unusual design feature associated with the installation of a Tamarack Active Technology Load Alleviation System and Cranfield Winglets. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These amended special conditions contain the additional safety standards the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards, change the Type Certificate holder, and remove the special flight permit requirement. **DATES:** These special conditions are effective July 19, 2018 and are applicable on July 10, 2018.

We must receive your comments by September 17, 2018.

ADDRESSES: Send comments identified by docket number FAA–2016–9409 using any of the following methods:

☐ Federal eRegulations Portal: Go to http://www.regulations.gov and follow the online instructions for sending your comments electronically.

- ☐ Mail: Send comments to Docket Operations, M-30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.
- ☐ Hand Delivery of Courier: Deliver comments to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- ☐ *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to http://regulations.gov, including any personal information the commenter provides. Using the search function of the docket website, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the Federal Register published on April 11, 2000 (65 FR 19477-19478), as well as at http://DocketsInfo.dot.gov.

Docket: You can read the background documents or comments received at http://www.regulations.gov. Follow the online instructions for accessing the docket or go to the Docket Operations in Room @12–140 of the West Building

Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Mike Reyer, Continued Operational Safety, ACE-113, Small Airplane Directorate, Aircraft Certification Service, 901 Locust, Kansas City, Missouri 64106; telephone (816) 329-4131; facsimile (816) 329-4090.

SUPPLEMENTARY INFORMATION:

Reason for No Prior Notice and Comment Before Adoption

These special conditions have been subjected to the notice and comment period previously and this amendment is without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary and finds good cause exists for adopting these amended special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment.

Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We will consider all comments we receive by the closing date for comments.

We will consider comments filed late if it is possible to do so without incurring additional expense or delay. We may change these special conditions based on the comments we receive.

Background

On January 25, 2016, Cranfield Aerospace Limited (CAL) applied for a supplemental type certificate to install winglets on the Textron Aviation Inc. (Textron) Model 525, with a Tamarack Active Technology Load Alleviation System to mitigate the winglet's adverse structural effects. The Textron Model 525 twin-turbofan engine airplane is certified in the normal category for eight seats, including a pilot, a maximum gross weight of 10,700 pounds, and a maximum altitude of 41,000 feet mean sea level. Because the applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature, the FAA issued special conditions to provide an

equivalent level of safety. After notice and opportunity for comment (81 FR 83737, November 22, 2016), Special Conditions No. 23–279–SC published in the Federal Register on January 5, 2017 (82 FR 1163).

These special conditions address several issues with the operation and failure of the load-relief system. Special Conditions No. 23–279–SC, paragraph 2(h), Further flights with known loadrelief system failure, required a special flight permit ("ferry permit") for additional flights after an annunciated failure or obvious system failure.

On February 15, 2018, CAL requested the FAA amend Special Condition No. 23-279-SC to remove the paragraph 2(h) and replace it with flight limitations used by the European Aviation Safety Agency. In the event of a load-relief system failure, these flight limitations allow the airplane to be moved to an appropriate maintenance facility without the need for a special

flight permit.

The FAA will amend the special conditions to remove the special flight permit requirements, but finds no need to include any additional requirement regarding flights with known load relief system failure in these special conditions. Current regulatory requirements address this condition. Inoperative equipment requirements are contained in 14 CFR part 91. Section 91.213, Inoperative instruments and equipment, prohibits taking off in an aircraft with inoperative instruments or equipment unless there is an FAAapproved Minimum Equipment List (MEL) for the specific aircraft type. Without an FAA-approved MEL, operators must obtain a special flight permit in accordance with §§ 21.197, Special flight permits, and 21.199, Issue of special flight permits. Additional operational restrictions are not necessary for these special conditions.

On July 29, 2015, Čessna Aircraft Company transferred Type Certificate No. A1WI to Textron. As a result, these proposed amended special conditions reflect the current type certificate holder. In addition, these special conditions were intended to apply to all Model 525 airplanes on Type Certificate No. A1WI, and we have clarified that in this amendment.

Type Certification Basis

Under the provisions of § 21.101, Cranfield Aerospace Limited must show that the Textron Model 525-series airplanes, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A1WI, revision 26, or the applicable regulations in effect on

the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the "original type certification basis." The regulations incorporated by reference in Type Certificate No. A1WI, revision 26, are 14 CFR part 23 effective February 1, 1965, amendments 23-1 through 23-38 and 23 - 40.

If the Administrator finds the applicable airworthiness regulations (i.e., 14 CFR part 23) do not contain adequate or appropriate safety standards for the Textron Model 525-series because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Textron Model 525series must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should the applicant apply for a supplemental type certificate to modify any other model included on the same type certificate to incorporate the same or similar novel or unusual design feature, the FAA would apply these special conditions to the other model under § 21.101.

Novel or Unusual Design Features

The Textron Model 525-series will incorporate the following novel or unusual design features:

Cranfield winglets with a Tamarack Active Technology Load Alleviation System.

Discussion

For airplanes equipped with systems that affect structural performance, either directly or as a result of a failure or malfunction, the applicant must take into account the influence of these systems and their failure conditions when showing compliance with the requirements of part 23, subparts C and D.

The applicant must use the following criteria for showing compliance with these special conditions for airplanes equipped with flight control systems, autopilots, stability augmentation systems, load alleviation systems, flutter control systems, fuel management systems, and other systems that either

directly or as a result of failure or malfunction affect structural performance. If these special conditions are used for other systems, it may be necessary to adapt the criteria to the specific system.

Discussion of Comments

Notice of proposed Special Conditions No. 23–16–03–SC for the Cessna Model 525 airplane was published in the **Federal Register** on November 22, 2016 (81 FR 83737). No comments were received, and the special conditions were adopted—as proposed—in Special Condition No. 23–279–SC (82 FR 1163, January 5, 2017). Accordingly, these amended special conditions are being issued as final special conditions.

Applicability

As discussed above, these special conditions are applicable to the Textron Model 525-series airplanes. Should Cranfield Aerospace Limited apply at a later date for a supplemental type certificate to modify any other model included on A1WI, revision 26, to incorporate the same novel or unusual design feature, the FAA would apply these special conditions to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 14 CFR 21.16, 21.101; and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Textron Aviation Inc. Model 525-series airplanes modified by Cranfield Aerospace Limited.

1. Active Technology Load Alleviation System (ATLAS)

SC 23.672 Load Alleviation System

The load alleviation system must comply with the following:

- (a) A warning, which is clearly distinguishable to the pilot under expected flight conditions without requiring the pilot's attention, must be provided for any failure in the load alleviation system or in any other automatic system that could result in an unsafe condition if the pilot was not aware of the failure. Warning systems must not activate the control system.
- (b) The design of the load alleviation system or of any other automatic system must permit initial counteraction of failures without requiring exceptional pilot skill or strength, by either the deactivation of the system or a failed portion thereof, or by overriding the failure by movement of the flight controls in the normal sense.
- (1) If deactivation of the system is used to counteract failures, the control for this initial counteraction must be readily accessible to each pilot while operating the control wheel and thrust control levers.
- (2) If overriding the failure by movement of the flight controls is used, the override capability must be operationally demonstrated.
- (c) It must be shown that, after any single failure of the load alleviation system, the airplane must be safely controllable when the failure or malfunction occurs at any speed or altitude within the approved operating limitations that is critical for the type of failure being considered:
- (d) It must be shown that, while the system is active or after any single failure of the load alleviation system—
- (1) The controllability and maneuverability requirements of part 23, subpart D, are met within a practical operational flight envelope (e.g., speed, altitude, normal acceleration, and airplane configuration) that is described in the Airplane Flight Manual (AFM); and
- (2) The trim, stability, and stall characteristics are not impaired below a level needed to permit continued safe flight and landing.

SC 23.677 Load Alleviation Active Control Surface

- (a) Proper precautions must be taken to prevent inadvertent or improper operation of the load alleviation system. It must be demonstrated that with the load alleviation system operating throughout its operational range, a pilot of average strength and skill level is able to continue safe flight with no objectionable increased workload.
- (b) The load alleviation system must be designed so that, when any one connecting or transmitting element in the primary flight control system fails,

adequate control for safe flight and landing is available.

- (c) The load alleviation system must be irreversible unless the control surface is properly balanced and has no unsafe flutter characteristics. The system must have adequate rigidity and reliability in the portion of the system from the control surface to the attachment of the irreversible unit to the airplane structure.
- (d) It must be demonstrated the airplane is safely controllable and a pilot can perform all maneuvers and operations necessary to affect a safe landing following any load alleviation system runaway not shown to be extremely improbable, allowing for appropriate time delay after pilot recognition of the system runaway. The demonstration must be conducted at critical airplane weights and center of gravity positions.

SC 23.683 Operation Tests

- (a) It must be shown by operation tests that, when the flight control system and the load alleviation systems are operated and loaded as prescribed in paragraph (c) of this section, the flight control system and load alleviation systems are free from—
 - (1) Jamming;
 - (2) Excessive friction; and
 - (3) Excessive deflection.
- (b) The operation tests in paragraph (a) of this section must also show the load alleviation system and associated surfaces do not restrict or prevent aileron control surface movements, or cause any adverse response of the ailerons, under the loading prescribed in paragraph (c) of this section that would prevent continued safe flight and landing
- (c) The prescribed test loads are for the entire load alleviation and flight control systems, loads corresponding to the limit air loads on the appropriate surfaces.

Note: Advisory Circular (AC) 23–17C, "Systems and Equipment Guide to Certification of Part 23 Airplanes," provides guidance on potential methods of compliance with this section and other regulations applicable to this STC project.

SC 23.685 Control System Details

- (a) Each detail of the load alleviation system and related moveable surfaces must be designed and installed to prevent jamming, chafing, and interference from cargo, passengers, loose objects, or the freezing of moisture.
- (b) There must be means in the cockpit to prevent the entry of foreign objects into places where they would

jam any one connecting or transmitting element of the load alleviation system.

(c) Each element of the load alleviation system must have design features, or must be distinctively and permanently marked, to minimize the possibility of incorrect assembly that could result in malfunctioning of the control system.

SC 23.697 Load Alleviation System Controls

- (a) The load alleviation control surface must be designed so that during normal operation, when the surface has been placed in any position, it will not move from that position unless the control is adjusted or is moved by the operation of a load alleviation system.
- (b) The rate of movement of the control surface in response to the load alleviation system controls must give satisfactory flight and performance characteristics under steady or changing conditions of airspeed, engine power, attitude, flap configuration, speedbrake position, and during landing gear extension and retraction.

SC 23.701 Load Alleviation System Interconnection

- (a) The load alleviation system and related movable surfaces as a system must—
- (1) Be synchronized by a mechanical interconnection between the movable surfaces or by an approved equivalent means; or
- (2) Be designed so the occurrence of any failure of the system that would result in an unsafe flight characteristic of the airplane is extremely improbable; or
- (b) The airplane must be shown to have safe flight characteristics with any combination of extreme positions of individual movable surfaces.
- (c) If an interconnection is used in multiengine airplanes, it must be designed to account for unsymmetrical loads resulting from flight with the engines on one side of the plane of symmetry inoperative and the remaining engines at takeoff power. For single-engine airplanes, and multiengine airplanes with no slipstream effects on the load alleviation system, it may be assumed that 100 percent of the critical air load acts on one side and 70 percent on the other.

Sections 23.675, "Stops;" 23.681, "Limit Load Static Tests;" and 23.693, "Joints"

The load alleviation system must comply with §§ 23.675, 23.681, and 23.693 as written and no unique special condition will be required for these regulations.

Applicability of Control System Regulations to Other Control Systems

If applicable, other control systems used on the Textron Model 525-series may require a showing of compliance with §§ 23.672, 23.675, 23.677, 23.681, 23.683, 23.685, 23.693, 23.697, and 23.701 as written for this STC project.

2. Interaction of Systems and Structures

- (a) The criteria defined herein only address the direct structural consequences of the system responses and performances and cannot be considered in isolation but should be included in the overall safety evaluation of the airplane. These criteria may in some instances duplicate standards already established for this evaluation. These criteria are only applicable to structure whose failure could prevent continued safe flight and landing. Specific criteria that define acceptable limits on handling characteristics or stability requirements when operating in the system degraded or inoperative mode are not provided in this special condition.
- (b) Depending upon the specific characteristics of the airplane, additional studies may be required that go beyond the criteria provided in this special condition in order to demonstrate the capability of the airplane to meet other realistic conditions such as alternative gust or maneuver descriptions for an airplane equipped with a load alleviation system.

(c) The following definitions are applicable to this special condition.

(1) Structural performance: Capability of the airplane to meet the structural requirements of 14 CFR part 23.

- (2) Flight limitations: Limitations that can be applied to the airplane flight conditions following an in-flight occurrence and that are included in the flight manual (e.g., speed limitations, avoidance of severe weather conditions, etc.).
 - (3) Reserved.
- (4) Probabilistic terms: The probabilistic terms (probable, improbable, extremely improbable) used in this special condition are the same as those used in § 23.1309. For the purposes of this special condition, extremely improbable for normal, utility, and acrobatic category airplanes is defined as 10⁻⁸ per hour. For commuter category airplanes, extremely improbable is defined as 10⁻⁹ per hour.

(5) Failure condition: The term failure condition is the same as that used in § 23.1309, however this special condition applies only to system failure conditions that affect the structural performance of the airplane (e.g., system

failure conditions that induce loads, change the response of the airplane to inputs such as gusts or pilot actions, or lower flutter margins).

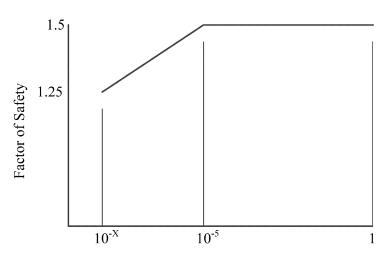
(d) General. The following criteria (paragraphs (e) through (i)) will be used in determining the influence of a system and its failure conditions on the airplane structure.

(e) System fully operative. With the system fully operative, the following

apply:

- (1) Limit loads must be derived in all normal operating configurations of the system from all the limit conditions specified in subpart C (or defined by special condition or equivalent level of safety in lieu of those specified in subpart C), taking into account any special behavior of such a system or associated functions or any effect on the structural performance of the airplane that may occur up to the limit loads. In particular, any significant nonlinearity (rate of displacement of control surface, thresholds or any other system nonlinearities) must be accounted for in a realistic or conservative way when deriving limit loads from limit conditions.
- (2) The airplane must meet the strength requirements of part 23 (static strength and residual strength for failsafe or damage tolerant structure), using the specified factors to derive ultimate loads from the limit loads defined above. The effect of nonlinearities must be investigated beyond limit conditions to ensure the behavior of the system presents no anomaly compared to the behavior below limit conditions. However, conditions beyond limit conditions need not be considered when it can be shown that the airplane has design features that will not allow it to exceed those limit conditions.
- (3) The airplane must meet the aeroelastic stability requirements of § 23.629.
- (f) System in the failure condition. For any system failure condition not shown to be extremely improbable, the following apply:
- (1) At the time of occurrence. Starting from 1-g level flight conditions, a realistic scenario, including pilot corrective actions, must be established to determine the loads occurring at the time of failure and immediately after failure.
- (i) For static strength substantiation, these loads, multiplied by an appropriate factor of safety that is related to the probability of occurrence of the failure, are ultimate loads to be considered for design. The factor of safety is defined in figure 1.

Figure 1—Factor of Safety at the Time of Occurrence



P_i, Probability of occurrence of failure mode j (per hour)

 $10^{-X} = 10^{-8}$ for Normal, Utility, and Acrobatic Category Airplanes = 10^{-9} for Commuter Category Airplanes

(ii) For residual strength substantiation, the airplane must be able to withstand two thirds of the ultimate loads defined in subparagraph (f)(1)(i).

(iii) For pressurized cabins, these loads must be combined with the normal operating differential pressure.

(iv) Freedom from aeroelastic instability must be shown up to the speeds defined in § 23.629(f). For failure conditions that result in speeds beyond V_D/M_D , freedom from aeroelastic instability must be shown to increased speeds, so that the margins intended by § 23.629(f) are maintained.

(v) Failures of the system that result in forced structural vibrations (oscillatory failures) must not produce loads that could result in detrimental deformation of primary structure. (2) For the continuation of the flight. For the airplane, in the system failed state and considering any appropriate reconfiguration and flight limitations, the following apply:

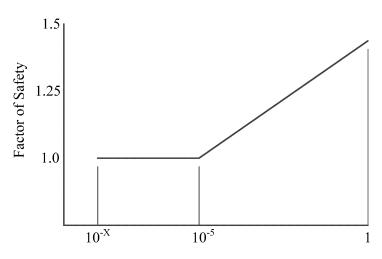
(i) The loads derived from the following conditions (or defined by special condition or equivalent level of safety in lieu of the following conditions) at speeds up to $V_{\rm C}/M_{\rm C}$, or the speed limitation prescribed for the remainder of the flight, must be determined:

(A) The limit symmetrical maneuvering conditions specified in §§ 23.321, 23.331, 23.333, 23.345, 23.421, 23.423, and 23.445.

(B) The limit gust and turbulence conditions specified in §§ 23.341, 23.345, 23.425, 23.443, and 23.445.

- (C) The limit rolling conditions specified in § 23.349 and the limit unsymmetrical conditions specified in §§ 23.347, 23.427, and 23.445.
- (D) The limit yaw maneuvering conditions specified in §§ 23.351, 23.441, and 23.445.
- (E) The limit ground loading conditions specified in §§ 23.473 and 23.493.
- (ii) For static strength substantiation, each part of the structure must be able to withstand the loads in paragraph (f)(2)(i) of this special condition multiplied by a factor of safety depending on the probability of being in this failure state. The factor of safety is defined in figure 2.

Figure 2—Factor of Safety for Continuation of Flight



Q_i, Probability of Being in Failure Condition j

10^{-X} = 10⁻⁸ for Normal, Utility, and Acrobatic Category Airplanes = 10⁻⁹ for Commuter Category Airplanes

 $Q_i = (T_i)(P_i)$ where:

 T_i = Average time spent in failure condition j, hours

P_i = Probability of occurrence of failure mode j, per hour

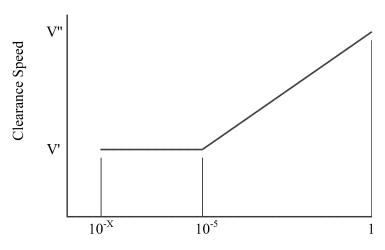
Note: If P_j is greater than 10^{-3} per flight hour then a 1.5 factor of safety must be applied to all limit load conditions specified in part 23 subpart C.

(iii) For residual strength substantiation, the airplane must be able to withstand two thirds of the ultimate loads defined in paragraph (f)(2)(ii) of this special condition. For pressurized cabins, these loads must be combined

with the normal operating pressure differential.

(iv) If the loads induced by the failure condition have a significant effect on fatigue or damage tolerance then their effects must be taken into account. (v) Freedom from aeroelastic instability must be shown up to a speed determined from figure 3. Flutter clearance speeds V' and V" may be based on the speed limitation specified for the remainder of the flight using the margins defined by § 23.629.

Figure 3—Clearance Speed



Q_i, Probability of Being in Failure Condition j

 $10^{-X} = 10^{-8}$ for Normal, Utility, and Acrobatic Category Airplanes = 10^{-9} for Commuter Category Airplanes

V' = Clearance speed as defined by §23.629(f) V" = Clearance speed as defined by §23.629(b)

 $Q_i = (T_i)(P_i)$ where:

 T_i = Average time spent in failure condition j, hours

P_i = Probability of occurrence of failure mode j, per hour

Note: If P_j is greater than 10^{-3} per flight hour then the flutter clearance speed must not be less than V"

- (vi) Freedom from aeroelastic instability must also be shown up to V' in figure 3 above, for any probable system failure condition combined with any damage required or selected for investigation by §§ 23.571 through 23.574.
- (3) Consideration of certain failure conditions may be required by other sections of 14 CFR part 23 regardless of calculated system reliability. Where analysis shows the probability of these failure conditions to be less than 10^{-8} for normal, utility, or acrobatic category airplanes or less than 10^{-9} for commuter category airplanes, criteria other than those specified in this paragraph may be used for structural substantiation to show continued safe flight and landing.
- (g) Failure indications. For system failure detection and indication, the following apply:
- (1) The system must be checked for failure conditions, not extremely improbable, that degrade the structural
- capability below the level required by part 23 or significantly reduce the reliability of the remaining system. As far as reasonably practicable, the flightcrew must be made aware of these failures before flight. Certain elements of the control system, such as mechanical and hydraulic components, may use special periodic inspections, and electronic components may use daily checks, in lieu of detection and indication systems to achieve the objective of this requirement. These certification maintenance requirements must be limited to components that are not readily detectable by normal detection and indication systems and where service history shows that inspections will provide an adequate level of safety.
- (2) The existence of any failure condition, not extremely improbable, during flight that could significantly affect the structural capability of the airplane and for which the associated reduction in airworthiness can be

- minimized by suitable flight limitations, must be signaled to the flightcrew. The probability of not annunciating these failure conditions must be extremely improbable (unannunciated failure). For example, failure conditions that result in a factor of safety between the airplane strength and the loads of subpart C below 1.25, or flutter margins below V", must be signaled to the flightcrew during flight.
- (h) Fatigue and damage tolerance. If any system failure would have a significant effect on the fatigue or damage evaluations required in §§ 23.571 through 23.574, then these effects must be taken into account.

Issued in Kansas City, Missouri, on July 10, 2018.

Pat Mullen,

Manager, Small Airplane Standard Branch, Aircraft Certification Service.

[FR Doc. 2018–15354 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0091; Product Identifier 2017-SW-054-AD; Amendment 39-19334; AD 2018-15-02]

RIN 2120-AA64

Airworthiness Directives; Airbus Helicopters

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

ACTION: Final rule; request for

comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters. This AD requires inspecting the tail rotor (TR) pitch rod. This AD is prompted by a report of several cases of damaged TR pitch rod ball joints. The actions of this AD are intended to correct an unsafe condition on these helicopters.

DATES: This AD becomes effective August 3, 2018.

We must receive comments on this AD by September 17, 2018.

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 by searching for and locating Docket No. FAA-2018-0091; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (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 final rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT:

David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email david.hatfield@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, 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 resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, 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 them 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 rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued Emergency AD No. 2017–0020–E, dated February 7, 2017, to correct an unsafe condition for Airbus Helicopters Model AS 350 B, AS 350 BA, AS 350 BB, AS 350 B1, AS 350 B2, AS 350 B3, AS 355 E, AS 355 F, AS 355 F1, AS 355 F2, AS 355 N and AS 355 NP helicopters with modification (MOD) 075601 or MOD 076602 installed. EASA advises of several

reports of damaged horn-side TR pitch rod elastomeric ball joints, and of an ongoing investigation to determine the cause of the damage. EASA states that this condition could result in loss of control of the helicopter. To address this unsafe condition, the EASA AD requires repetitive inspections of the TR pitch rod. While the inspections are contained in the Airworthiness Limitations Section of the helicopter maintenance manual, the EASA AD reduces the interval from 50 flight hours to 10 flight hours.

FAA's Determination

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

Related Service Information

We reviewed Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05.00.86 for Model AS350-series helicopters and EASB No. 05.00.75 for Model AS355-series helicopters, both Revision 1 and both dated February 6, 2017. This service information contains procedures for inspecting the TR pitch change rod elastomeric ball joint for damage.

AD Requirements

This AD requires, for helicopters with a TR pitch change rod elastomeric ball joint installed, within 10 hours time-inservice (TIS) and thereafter at intervals not exceeding 10 hours TIS, inspecting each face of the TR pitch rod blade side ball joint for debonding, extrusion, and a crack. If there is debonding, extrusion, or a crack with a circumference of 90 degrees or more, this AD requires replacing the TR pitch rod before further flight. Airbus Helicopters identifies the installation of a TR pitch change rod elastomeric ball joint as MOD 075601 or MOD 076602.

Differences Between This AD and the EASA AD

The EASA AD applies to Airbus Helicopters Model AS 350 BB helicopters. This AD does not as that model is not type-certificated in the U.S.

Interim Action

We consider this AD to be an interim action. If final action is later identified,

we might consider further rulemaking then.

Costs of Compliance

We estimate that this AD affects 896 helicopters of U.S. Registry.

We estimate that operators may incur the following costs in order to comply with this AD. At an average labor rate of \$85 per hour, inspecting the TR pitch rod ball joint requires 0.5 hour, for a cost of \$43 per helicopter and \$38,528 for the U.S. fleet, per inspection cycle.

If required, replacing a TR pitch rod requires one work-hour and required parts cost \$3,174, for a cost per helicopter of \$3,259.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because the inspections required by this AD must be accomplished within 10 hours TIS and thereafter every 10 hours TIS. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reason stated above, we find that good cause exists for making this amendment effective in less than 30 days.

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, I certify that this AD:

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2018-15-02 Airbus Helicopters:

Amendment 39–19334; Docket No. FAA–2018–0091; Product Identifier 2017–SW–054–AD.

(a) Applicability

This AD applies to Airbus Helicopters Model AS350B, AS350B1, AS350B2, AS350B3, AS350BA, AS355E, AS355F, AS355F1, AS355F2, AS355N, and AS355NP helicopters, certificated in any category, with a tail rotor (TR) pitch change rod elastomeric ball joint installed.

Note 1 to paragraph (a): Airbus Helicopters modification (MOD) 075601 and MOD 076602 consist of replacing the TR pitch change rod with an elastomeric ball joint rod.

(b) Unsafe Condition

This AD defines the unsafe condition as a damaged elastomeric ball joint on the TR pitch change rod. This condition could result in failure of the TR pitch change rod and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective August 3, 2018.

(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 10 hours time-in-service (TIS) and thereafter at intervals not exceeding 10 hours TIS:

- (1) Manually induce a flapping movement in the TR blade until the pitch change rod rotates a minimum of 10 degrees.
- (2) Inspect both faces of the blade side of the ball joint elastomer for debonding, extrusion, and cracks. If there is a crack or any debonding or extrusion with a circumference of 90 or more degrees, before further flight, replace the pitch change rod.

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

- (1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9–ASW–FTW–AMOC-Requests@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.

(h) Additional Information

(1) Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05.00.86 and EASB No. 05.00.75, both Revision 1 and both dated February 6, 2017, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at http://

www.helicopters.airbus.com/website/en/ref/ Technical-Support_73.html. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N– 321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) Emergency AD No. 2017–0020–E, dated February 7, 2017. You may view the EASA Emergency AD on the internet at http://www.regulations.gov by searching for and locating it in Docket No. FAA–2018–0091.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6720 Tail Rotor Control System. Issued in Fort Worth, Texas, on July 6, 2018.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–15303 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0166; Product Identifier 2017-NM-169-AD; Amendment 39-19331; AD 2018-14-11]

RIN 2120-AA64

Airworthiness Directives; ATR-GIE Avions de Transport Régional Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all ATR–GIE Avions de Transport Régional Model ATR72 airplanes. This AD was prompted by a determination that more restrictive maintenance instructions and airworthiness limitations are necessary. This AD requires revising the maintenance or inspection program, as applicable, to incorporate new or revised maintenance instructions and airworthiness limitations. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 23, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 23, 2018.

ADDRESSES: For service information identified in this final rule, contact ATR–GIE Avions de Transport Régional, 1, Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email continued.airworthiness@atraircraft.com. You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available on the internet at http:// www.regulations.gov by searching for and locating Docket No. FAA-2018-0166.

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-2018-0166; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800-647-5527) is in the ADDRESSES section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT:

Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

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 all ATR-GIE Avions de Transport Régional Model ATR72 airplanes. The NPRM published in the Federal Register on March 22, 2018 (83 FR 12508). The NPRM was prompted by a determination that more restrictive maintenance instructions and airworthiness limitations are necessary. The NPRM proposed to require revising the maintenance or inspection program, as applicable, to incorporate new or revised maintenance instructions and airworthiness limitations. We are issuing this AD to address fatigue cracking, damage, and corrosion in principal structural elements, which could result in reduced structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0223R1, dated December 15, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for all ATR–GIE Avions de Transport Régional Model ATR72 airplanes. The MCAI states:

The airworthiness limitations and certification maintenance requirements (CMR) for ATR aeroplanes, which are approved by EASA, are currently defined and published in the ATR72–101/–201/–102/–202/–211/–212/–212A Time Limits (TL) document. These instructions have been identified as mandatory actions for continued airworthiness.

Failure to accomplish these instructions could result in an unsafe condition.

Consequently, ATR published Revision 15 of the ATR72–101/–201/–102/–202/–211/–212/–212A TL document, which contains new and/or more restrictive CMRs and airworthiness limitation tasks.

For the reasons described above, this [EASA] AD requires accomplishment of the actions specified in the ATR72–101/–201/–102/–202/–211/–212/–212A TL document Revision 15, hereafter referred to as 'the TLD' in this [EASA] AD.

This [EASA] AD, in conjunction with two other [EASA] ADs related to ATR42–200/–300/–320 (EASA AD 2017–0221) and ATR42–400/–500 (EASA AD 2017–0222) aeroplanes, retains the requirements of EASA AD 2009–0241 and EASA AD 2012–0193. Once all these three ADs are effective, EASA will cancel EASA AD 2009–0242 and EASA AD 2012–0193.

This [EASA] AD is revised to provide the correct issue date (02 May 2017) of the TLD. The original [EASA] AD inadvertently referenced the EASA approval date for that document.

This AD requires revising the maintenance or inspection program to incorporate certain maintenance instructions and airworthiness limitations. The unsafe condition is fatigue cracking, damage, and corrosion in principal structural elements, which could result in reduced structural integrity of the airplane. 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—2018—0166.

Comment

We gave the public the opportunity to participate in developing this final rule. The following presents the comment received on the NPRM and the FAA's response.

Request To Correct Typographical Error

Empire Airlines asked that airworthiness limitations (AWL) task number 572401–1, identified in table 1 to paragraph (h) of this AD, be changed to AWL task number 572402–1. Empire Airlines stated that AWL task number 572401–1 corresponds to maintenance review board report (MRBR) task numbers ZL–500–01–1 and ZL–600–01–1; and the MRBR task numbers ZL–520–01–1 and ZL–620–01–1, identified in table 1 to paragraph (h) of this AD, correspond with AWL task number 572402–1. Empire Airlines provided substantiation data to this effect.

We agree with the commenter that a typographical error was made in the AWL task number 572401–1, identified in table 1 to paragraph (h) of this AD. We have corrected this error accordingly.

Airworthiness Limitations Based on Type Design

The FAA recently became aware of an issue related to the applicability of ADs that require incorporation of an airworthiness limitations section (ALS) revision into an operator's maintenance or inspection program.

Typically, when these types of ADs are issued by civil aviation authorities of other countries, they apply to all airplanes covered under an identified type certificate (TC). The corresponding FAA AD typically retains applicability

to all of those airplanes.

In addition, U.S. operators must operate their airplanes in an airworthy condition, in accordance with 14 CFR 91.7(a). Included in this obligation is the requirement to perform any maintenance or inspections specified in the ALS, and in accordance with the ALS as specified in 14 CFR 43.16 and 91.403(c), unless an alternative has been approved by the FAA.

When a type certificate is issued for a type design, the specific ALS, including revisions, is a part of that type design, as specified in 14 CFR 21.31(c).

The sum effect of these operational and maintenance requirements is an obligation to comply with the ALS defined in the type design referenced in the manufacturer's conformity statement. This obligation may introduce a conflict with an AD that requires a specific ALS revision if new airplanes are delivered with a later revision as part of their type design.

To address this conflict, the FAA has approved alternative methods of compliance (AMOCs) that allow operators to incorporate the most recent ALS revision into their maintenance/ inspection programs, in lieu of the ALS revision required by the AD. This eliminates the conflict and enables the operator to comply with both the AD

and the type design.

However, compliance with AMOCs is normally optional, and we recently became aware that some operators choose to retain the AD-mandated ALS revision in their fleet-wide maintenance/inspection programs, including those for new airplanes delivered with later ALS revisions, to help standardize the maintenance of the fleet. To ensure that operators comply with the applicable ALS revision for newly delivered airplanes containing a later revision than that specified in an AD, we plan to limit the applicability of ADs that mandate ALS revisions to those airplanes that are subject to an earlier revision of the ALS, either as part of the type design or as mandated by an earlier AD.

This AD therefore applies to ATR–GIE Avions de Transport Régional Model ATR72-101, -102, -201, -202, -211, –212, and –212A airplanes with an original certificate of airworthiness or original export certificate of airworthiness that was issued on or before the date of approval of the ALS revision identified in this AD. Operators of airplanes with an original certificate of airworthiness or original export certificate of airworthiness issued after that date must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule 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 for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

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

Related Service Information Under 1 CFR Part 51

ATR–GIE Avions de Transport Régional has issued the ATR72 Time Limits document, Revision 15, dated May 2, 2017. This service information describes preventive maintenance requirements and includes updated limitations, tasks, thresholds and intervals to be incorporated into the maintenance or inspection program. 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.

Costs of Compliance

We estimate that this AD affects 26 airplanes of U.S. registry.

We estimate the following costs to

comply with this AD:

We have determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program

changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a perairplane estimate. Therefore, we estimate the total cost per operator to be \$7,650 (90 work-hours × \$85 per workhour).

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

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

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 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.

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):

2018–14–11 ATR–GIE Avions de Transport Régional: Amendment 39–19331; Docket No. FAA–2018–0166; Product Identifier 2017–NM–169–AD.

(a) Effective Date

This AD is effective August 23, 2018.

(b) Affected ADs

This AD affects AD 2000–23–26, Amendment 39–11999 (65 FR 70775, November 28, 2000) ("AD 2000–23–26"); and AD 2008–04–19 R1, Amendment 39–16069 (74 FR 56713, November 3, 2009) ("AD 2008– 04–19 R1").

(c) Applicability

This AD applies to ATR–GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes, certificated in any category; with an original certificate of airworthiness or original export certificate of airworthiness issued on or before May 2, 2017.

(d) Subject

Air Transport Association (ATA) of America Code 05.

(e) Reason

This AD was prompted by a determination that more restrictive maintenance instructions and airworthiness limitations are necessary. We are issuing this AD to prevent fatigue cracking, damage, and corrosion in principal structural elements, 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) Revision of Maintenance or Inspection Program

Within 90 days after the effective date of this AD: Revise the maintenance or inspection program, as applicable, to incorporate the limitations and tasks at the applicable thresholds and intervals specified in the Airworthiness Limitations Section (ALS), of the ATR72 Time Limits document, Revision 15, dated May 2, 2017. The initial compliance time for accomplishing the tasks specified in the ALS of the ATR72 Time Limits document, Revision 15, dated May 2, 2017, is at the applicable time specified in the ALS, or within 90 days after the effective date of this AD, whichever occurs later, except for the tasks identified in paragraph (h) of this AD.

(h) Initial Compliance Times for Certain Tasks

For accomplishing airworthiness limitations (AWL) and certification maintenance requirement (CMR)/maintenance significant item (MSI) tasks identified in table 1 and table 2 to paragraph (h) of this AD, the initial compliance time is at the applicable time specified in the ALS of the ATR72 Time Limits document, Revision 15, dated May 2, 2017, or at the applicable compliance time in table 1 or table 2 to paragraph (h) of this AD, whichever occurs later.

Table 1 to paragraph (h) of this AD – Grace period for structurally significant

item (SSI) task

| AWL Task | Compliance Time |
|----------|--|
| 572402-1 | Within 5,000 flight hours after the most recent inspection done as specified in Maintenance Review Board Report (MRBR) tasks ZL-520-01-1 and ZL-620-01-1 |

Table 2 to paragraph (h) of this AD – Grace period for CMR/MSI tasks

| CMR/MSI Tasks | Compliance Time |
|---------------|---|
| 213100-1 | Within 550 flight hours or 3 months after the |
| 213100-2 | effective date of this AD, whichever occurs |
| 213100-3 | first |

(i) No Alternative Actions, and Intervals

After the maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (e.g., inspections), or intervals, may be used unless the actions and/or intervals are approved as an alternative method of compliance (AMOC) in accordance with the

procedures specified in paragraph (k)(1) of this AD.

(j) Terminating Action

Accomplishing paragraph (g) of this AD terminates all requirements of AD 2000–23–26 and AD 2008–04–19 R1.

(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, International Section, Transport Standards Branch, 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 International Branch, send it to the attention of the person identified in paragraph (l)(2) of this AD. 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.

(2) Contacting the Manufacturer: 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 Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(l) Related Information

- (1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0223R1, dated December 15, 2017, 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–2018–0166.
- (2) For more information about this AD, contact Shahram Daneshmandi, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3220.

(m) 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 this AD specifies otherwise.
- (i) ATR72 Time Limits document, Revision 15, dated May 2, 2017.
 - (ii) Reserved.
- (3) For service information identified in this AD, contact ATR–GIE Avions de Transport Régional, 1, Allée Pierre Nadot, 31712 Blagnac Cedex, France; telephone +33 (0) 5 62 21 62 21; fax +33 (0) 5 62 21 67 18; email continued.airworthiness@atraircraft.com.
- (4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.
- (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/ibrlocations.html.

Issued in Des Moines, Washington, on July 3, 2018.

Michael Kaszycki,

BILLING CODE 4910-13-P

Acting Director, System Oversight Division, Aircraft Certification Service. [FR Doc. 2018–14809 Filed 7–18–18; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2017-1093; Product Identifier 2017-NM-018-AD; Amendment 39-19329; AD 2018-14-09]

RIN 2120-AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A318 series airplanes; Model A319 series airplanes; Model A320-211, -212, -214, -216, -231, -232, and -233 airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, and -232 airplanes. This AD was prompted by reports of early cracking on certain holes of the crossbeam splicing at certain fuselage frames. This AD requires repetitive inspections for cracking of the fastener holes in certain fuselage frames, and depending on airplane configuration, provides an optional terminating action to the repetitive inspections. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 23, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of August 23, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 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 Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206-231-3195. It is also available on the internet at http://www.regulations.gov by searching

for and locating Docket No. FAA-2017-

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-2017-1093; 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 street address for the Docket Office (telephone 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, DČ 20590.

FOR FURTHER INFORMATION CONTACT:

Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

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 Airbus Model A318 series airplanes; Model A319 series airplanes; Model A320-211, -212, -214, -216, -231, -232, and -233 airplanes; and Model A321-111, -112, -131, -211, -212, -213, -231, and -232 airplanes. The NPRM published in the Federal Register on November 27, 2017 (82 FR 55955) ("the NPRM"). The NPRM was prompted by reports of early cracking on certain holes of the crossbeam splicing at certain fuselage frames. The NPRM proposed to require repetitive inspections for cracking of the fastener holes in certain fuselage frames, and depending on airplane configuration, would provide an optional terminating action to the repetitive inspections. We are issuing this AD to address cracking at two upper rows of fasteners of the crossbeam splicing at frame (FR)16 and FR20, on both the left-hand (LH) and right-hand (RH) sides, which can result in reduced structural integrity of the airplane due to the failure of structural components.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016–0139, dated July 14, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition

for certain Model A318 series airplanes; Model A319 series airplanes; Model A320–211, –212, –214, –216, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

Following addition of a new airworthiness limitation item (ALI) task 531110 in the Airworthiness Limitation Section (ALS) Part 2 in the revision dated April 2012, numerous findings have been reported of early cracks on the four holes of the crossbeam splicing at frame (FR)16 and FR20 on both left-hand (LH) and right-hand (RH) sides.

This condition, if not detected and corrected, could affect the structural integrity of the airframe.

To allow an earlier crack detection, Airbus decided to transfer the repetitive inspections from ALI task 531110 to Airbus Service Bulletin (SB) A320–53–1286, later revised, including new recommended inspection thresholds.

For the reasons described above, this [EASA] AD requires repetitive special detailed [rototest] inspections (SDI) of the two upper rows of fasteners of the crossbeam splicing at FR16 and FR20, on both LH and RH sides, [installation of new fasteners on crack-free frames, related investigative and corrective actions,] and, depending on aeroplane configuration, provides an optional terminating action to the repetitive inspections required by this [EASA] AD.

Related investigative actions include checking the edge margins of the holes. Corrective actions include reaming affected crossbeams and frames and cold working the frames. 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—2017—1093.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM and the FAA's response to each comment.

Requests To Revise Repair Instructions for Repairs Done Using an Airbus Repair Design Approval Sheet (RDAS)

American Airlines (AAL) and United Airlines (UAL) requested that the repair instructions in paragraph (l) of the proposed AD be revised to remove requirements to obtain new repair instructions for any airplanes on which repairs were done using the instructions in an Airbus RDAS. AAL noted that the original RDAS approval was given by an EASA Design Organization Approval (DOA), so new approval should not be needed. Instead, AAL suggested that the issuer of the RDASs should be required to revise the RDASs as necessary. UAL noted that an RDAS already defines

repair life and inspection instructions or limits. UAL also noted that the MCAI does not require obtaining new repair instructions, but instead says to accomplish the repair instructions given in the RDAS for repaired fastener holes.

We disagree to require the issuer of the RDAS to revise the RDAS. An RDAS is an Airbus document that is not approved by the FAA, and the FAA has no authority to require Airbus to revise the RDAS.

We agree with the requests to remove the requirement to obtain repair instructions in paragraph (l) of this AD. We have confirmed that EASA intended the corresponding paragraph in the MCAI to be informational, rather than a new requirement. We have revised paragraph (l) of this AD to note that the information on the next inspection and compliance time for the inspection of repaired holes is specified in the applicable RDAS; therefore, there is no requirement to obtain and follow new instructions.

Request To Supersede Certain Inspections

UAL requested that we revise paragraph (l) of the proposed AD to state that previous repair instructions that superseded ALI 531110 also terminate the inspections required by paragraph (g) of the proposed AD for the repaired holes. UAL noted that they had several RDASs that state that the inspection requirements of the RDAS supersede ALI 531110 for the repaired fasteners. UAL stated that these repairs involved enlarging the holes and fasteners, thereby making it impossible for them to accomplish the inspections in accordance with Airbus Service Bulletin A320-53-1286, Revision 01, dated December 22, 2015.

We disagree with revising paragraph (l) of this AD to specify terminating action to paragraph (g) of this AD. An operator who is unable to complete certain requirements in this AD due to existing repairs may request an alternative method of compliance (AMOC) under the provisions of paragraph (s)(1) of this AD.

Request To Remove or Revise Paragraph (n) of the Proposed AD

AAL requested that paragraph (n) of the proposed AD be revised to remove requirements to obtain new repair instructions for any airplanes on which repairs were done using the instructions in an Airbus RDAS unrelated to ALI task 531110. AAL noted that the original RDAS approval was given by an EASA DOA, so new approval should not be needed. Instead, AAL suggested that the issuer of the RDASs should be required to revise the RDASs as necessary.

UAL requested that paragraph (n) of the proposed AD be removed. UAL stated that determining if a repair is unrelated to ALI task 531110 may be inconclusive, since the ALI task is an inspection that may or may not be referenced in a documented repair. UAL added that each repair approval will have damage tolerance considerations regardless of how the damage was found. UAL further noted that if a repair unrelated to ALI task 531110 prevents inspection or repair as specified in the proposed AD, operators would need to request an AMOC.

We disagree with the commenters' requests. EASA has determined that repairs unrelated to ALI task 531110, which could include minor repairs unrelated to the unsafe condition, may not adequately address the unsafe condition. For this reason, operators must request new corrective actions for such repairs, as specified in paragraph (n) of this AD.

Requests To Revise Repair Instructions for Airplanes on Which Certain Repairs Were Previously Applied

UAL and AAL requested that paragraphs (i) and (j) of the proposed AD be revised to list specific affected manufacturer serial numbers (MSNs). In addition, UAL and AAL requested that the original equipment manufacturer (OEM) revise the Airbus RDASs to correct any problems. AAL pointed out that the original RDAS was approved by an EASA DOA and stated that operators should therefore not be required to obtain a new approval. UAL requested that if we do not provide revised RDASs or a list of affected MSNs, we instead provide a pre-defined solution for the repair. UAL suggested that we should provide instructions for replacing EN6114 fasteners with EN6115 fasteners. UAL further requested that if the repairs require case-by-case evaluations, the repair instructions should define the repair compliance time, rather than having a set 24 month compliance time, which may not work for every configuration.

UAL also noted that the issue with Airbus Repair Instruction R53112926 issue A or B is that it called out the wrong fastener; EN6115 should have been used instead of EN6114.

UAL requested that we add a statement to paragraph (j) of this AD stating that no additional repair instructions are needed if a repair was accomplished using Airbus Repair Instruction R53112926 issue A or B and EN6115 fasteners.

We disagree with the commenters' requests to revise paragraphs (i) and (j) of this AD to list specific affected MSNs. EASA, as the state of design authority, and Airbus have both stated that they do not have knowledge of prior approved repairs; therefore we do not have a list of affected MSNs. In addition, an RDAS is an Airbus document that is not approved by the FAA, and the FAA has no authority to require Airbus to revise the RDAS. Therefore, each existing repair must be individually analyzed before a new corrective action can be provided. For this reason, we are not able to provide a single pre-defined solution for the repair that would address every affected configuration. We have determined that 24 months is an appropriate time frame to address the unsafe condition related to the EN6114 fasteners. An AMOC in accordance with paragraph (s)(1) of this AD may be requested if additional time is needed to address the unsafe condition.

We do not agree to add a statement to paragraphs (i) or (j) of this AD regarding no additional repair instructions are necessary if those repairs were applied with the installation of EN6115 fasteners, but we do agree to clarify that paragraphs (i) and (j) of this AD only apply to airplanes on which Airbus Repair Instruction R53112926 issue A or B or any other repair involving the installation of EN6114 fasteners was applied. If EN6115 fasteners were installed in the accomplishment of Airbus Repair Instruction R53112926 issue A or B or any other repair, the actions specified in paragraphs (i) or (j) of this AD are not required on the repaired airplane.

Request To Include Corrections to Service Information

UAL requested that we update paragraph (k) of the proposed AD to reflect corrections to Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015. UAL noted that Airbus has released Operators Information Transmission (OIT) 15–0097, Revision 01, dated January 7, 2016, to correct discrepancies in the effectivity section

and existing hole diameters for certain subtasks in Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015.

We agree with the commenter's request for the reasons provided. We have added paragraph (r) to this AD to clarify the hole-diameter correction provided in Airbus OIT 15-0097, Revision 01, dated January 7, 2016. We have also updated other paragraphs of this AD that refer to Airbus Service Bulletin A320-53-1295, including Appendixes 01 and 02, dated June 29, 2015, to include this exception. We also acknowledge the discrepancy in the effectivity section of Airbus Service Bulletin A320-53-1295, including Appendixes 01 and 02, dated June 29, 2015, and the correction provided in Airbus OIT 15-0097, Revision 01, dated January 7, 2016. However, the applicability of this AD does not refer to Airbus Service Bulletin A320-53-1295, including Appendixes 01 and 02, dated June 29, 2015. Therefore, we have not changed this AD in this regard.

Request To Verify Title of Table 1 to Paragraphs (g) and (n) of This AD

Virgin America requested that we review the title of table 1 to paragraphs (g) and (n) of this AD. Virgin America noted that the related MCAI table refers to airplanes having not embodied any of "mod 20416 and mod 21999," while the proposed AD refers to "pre-modification 20416 or pre-modification 21999" airplanes. Virgin America suggested this might be a typographical error, and asked that it be corrected if it is in error.

We acknowledge that the wording in the MCAI and this AD is not the same and agree to clarify. Table 1 of the MCAI is intended to apply to airplanes that have not embodied any part of modification 20416 or any part of modification 21999. Therefore, it is accurate to state "pre-modification 20416 or pre-modification 21999 airplanes." We have not changed this AD in this regard.

Request To Verify Referenced Service Information is at the Latest Revision

UAL requested that we verify the service bulletins referenced in the

proposed AD are at the latest revision level. UAL noted this would eliminate the need to request an AMOC immediately following publication of this AD.

We agree with the commenter's request. We have verified that no revisions of the referenced service information have been published since we issued our proposed AD.

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 changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

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

Airbus has issued the following service information.

- Service Bulletin A320–53–1286, Revision 01, dated December 22, 2015, which describes procedures for rototest inspections for cracking of the holes in certain fuselage frames and crossbeams.
- Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015, which describes procedures for modifying the airplane, including cold working instructions in certain fuselage frames and crossbeams.

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.

Costs of Compliance

We estimate that this AD affects 928 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|-----------------------|---|------------|-------------------------------|------------------------------|
| Inspections | | \$960 | \$10,820 per inspection cycle | ' ' . ' . ' |
| Optional Modification | tion cycle. 28 work-hours × times; \$85 per hour = \$2,380 | 3,020 | \$5,400 | cycle. Up to \$5,011,200. |

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions 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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866,

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

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):

2018–14–09 Airbus: Amendment 39–19329; Docket No. FAA–2017–1093; Product Identifier 2017–NM–018–AD.

(a) Effective Date

This AD is effective August 23, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A318–111, -112, -121, and -122 airplanes; Model A319–111, -112, -113, -114, -115, -131, -132, and -133 airplanes; Model A320–211, -212, -214, -216, -231, -232, and -233 airplanes; and Model A321–111, -112, -131, -211, -212, -213, -231, and -232 airplanes, certificated in any category, all manufacturer serial numbers, except the airplanes specified

- in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.
- (1) Airplanes on which Airbus modification 161255 has been embodied in production.
- (2) Model A319 series airplanes on which Airbus modifications 28238, 28162, and 28342 have been concurrently embodied in production.
- (3) Model A318 series airplanes on which Airbus modification 39195 has been embodied in production.

(d) Subject

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

(e) Reason

This AD was prompted by reports of early cracking on the four holes of the crossbeam splicing at certain fuselage frames (FR). We are issuing this AD to detect and correct cracking at two upper rows of fasteners of the crossbeam splicing at FR16 and FR20, on both the left-hand (LH) and right-hand (RH) sides, which can result in reduced structural integrity of the airplane due to the failure of structural components.

(f) Compliance

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

(g) Repetitive Rototest Inspections

Before exceeding the threshold specified in table 1 to paragraphs (g) and (n) of this AD, or table 2 to paragraphs (g) and (n) of this AD, as applicable to airplane configuration (preor post-modification 20416 or pre- or postmodification 21999): Do a special detailed (rototest) inspection of the two upper rows of fasteners of the crossbeam splicing at FR16 and FR20 on both LH and RH sides, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1286, Revision 01, dated December 22, 2015. Thereafter, repeat the inspection at the intervals specified in table 1 to paragraphs (g) and (n) of this AD, or table 2 to paragraphs (g) and (n) of this AD, as applicable to airplane configuration (pre- or postmodification 20416 or pre- or postmodification 21999).

BILLING CODE 4910-13-P

| Table 1 to paragraphs (g) and (n) | of this AD – <i>Inspection of pre-modification 20416 or</i> |
|-----------------------------------|--|
| pre-mo | dification 21999 airplanes |

| | 1 |
|------------------------------|--|
| | A: Before exceeding 36,800 flight cycles (FC) or 73,600 flight hours (FH), whichever occurs first since the first flight of the airplane |
| Threshold | B : Within 27,400 FC or 54,900 FH, whichever occurs first |
| (A or B or C, | since the last inspection as specified in airworthiness limitation |
| whichever occurs later) | item (ALI) task 531110-01-1 accomplished before the effective |
| | date of this AD |
| | C: Within 30 days after the effective date of this AD, without |
| | exceeding 38,800 FC or 77,600 FH, whichever occurs first |
| | since the first flight of the airplane |
| Repetitive Inspection | 27,400 FC or 54,900 FH, whichever occurs first |
| Interval | |
| (Not to exceed) | |

Table 2 to paragraphs (g) and (n) of this AD – Inspection of post-modification 20416 or post-modification 21999 airplanes

| | A: Before exceeding 34,700 FC or 69,400 FH, whichever |
|--------------------------------------|--|
| | occurs first since the first flight of the airplane |
| Threshold | B : Within 12,900 FC or 25,800 FH, whichever occurs first |
| (A or B or C , | since the last inspection as specified in ALI task 531110-01-2 |
| whichever occurs later) | accomplished before the effective date of this AD |
| | C: Within 30 days after the effective date of this AD, without |
| | exceeding 38,900 FC or 77,900 FH, whichever occurs first |
| | since the first flight of the airplane |
| Repetitive Inspection | 12,900 FC or 25,800 FH, whichever occurs first |
| Interval | |
| (Not to exceed) | |

BILLING CODE 4910-13-C

(h) Post-Inspection Actions

Depending on the results from any inspection required by paragraph (g) of this AD, do the actions in paragraphs (h)(1) or (h)(2) of this AD, as applicable.

(1) If, during any inspection required by paragraph (g) of this AD, any crack is detected: Before further flight, do all applicable related investigative and corrective actions in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320-53-1286, Revision 01, dated December 22, 2015; except where Airbus Service Bulletin A320-53-1286, Revision 01, dated December 22, 2015, specifies to contact Airbus for appropriate repair, and specifies that action as "RC" (Required for Compliance), accomplish corrective actions before further flight in accordance with the procedures specified in paragraph (s)(2) of this AD. Repair of an airplane as required by this paragraph does not constitute terminating action for the repetitive inspections required by paragraph

(g) of this AD for that airplane, unless specified otherwise in the repair instructions.

(2) If, during any inspection required by paragraph (g) of this AD, no cracks are detected: Before further flight, do all applicable fastener installations, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1286, Revision 01, dated December 22, 2015.

(i) Airplanes on Which Airbus Repair Instruction R53112926 With Installation of EN6114 Countersunk Fasteners Was Applied on the Frame and/or Crossbeam

For airplanes on which Airbus Repair Instruction R53112926 at issue A or B with installation of EN6114 countersunk fasteners was applied on the frame and/or crossbeam at FR16 LH or RH, or at FR20 LH or RH: Within 24 months after the effective date of this AD, modify the repair using a method approved by the Manager, International Section, Transport Standards Branch, 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.

(j) Airplanes on Which a Repair With Installation of EN6114 Countersunk Fasteners Was Applied on the Frame and/or Crossbeam

For airplanes on which a repair with installation of EN6114 countersunk fasteners, approved by the FAA, EASA, Airbus's EASA DOA, or an EASA DOA (other than Airbus's EASA DOA), was applied on the frame and/or crossbeam at FR16 LH or RH, or at FR20 LH or RH, in the area covered by paragraph (g) of this AD: Within 24 months after the effective date of this AD, modify the repair using a method approved by the Manager, International Section, Transport Standards Branch FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Optional Terminating Action for Airplanes Post-Modification 20416 or Post-Modification 21999

Modification of an airplane post-modification 20416 or post-modification 21999 in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015, except as required by paragraph (r) of this AD, constitutes terminating action for the repetitive inspections required by paragraph (g) of this AD for that airplane.

(l) Information on Post-Repair Actions for Certain Airplanes

For an airplane that has been inspected per ALI task 531110 and repaired before the effective date of this AD using the instructions in an Airbus Repair Design Approval Sheet (RDAS): each applicable RDAS contains next inspection and compliance time for the inspection for each repaired hole.

(m) Partial Terminating Action for Airplanes Post-Modification 20416 or Post-Modification 21999

For an airplane post-modification 20416 or post-modification 21999, modification in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015, except as required by paragraph (r) of this AD, for the applicable fastener holes, where no damage or cracks were detected (*i.e.*, those not repaired) during the latest inspection as required by paragraph (g) of this AD, constitutes terminating action for the repetitive inspections of those fastener holes as required by paragraph (g) of this AD for that airplane.

(n) Actions for Airplanes With Certain Repairs

For an airplane that has been repaired before the effective date of this AD in the areas described in this AD using the instructions in an Airbus RDAS unrelated to ALI task 531110: Before exceeding the compliance times specified in table 1 to paragraphs (g) and (n) of this AD or table 2 to paragraphs (g) and (n) of this AD, as applicable, contact the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA DOA for corrective action instructions and accomplish those instructions accordingly. If approved by the DOA, the approval must include the DOA-authorized signature. Accomplishment of corrective action(s) on an airplane, as required by this paragraph, does not constitute terminating action for the repetitive inspections required by paragraph (g) of this AD for that airplane, as applicable, unless specified otherwise in the instructions.

(o) Terminating Action for ALI Tasks

(1) Accomplishment of an inspection as required by paragraph (g) of this AD or instructions as required by paragraph (l) of this AD, as applicable, constitutes terminating action for the inspection requirements of ALI task 531110, for that airplane.

(2) Modification of the two upper rows of fasteners of the crossbeam splicing at FR16 and FR20 on both LH and RH sides of an airplane, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015, except as required by paragraph (r) of this AD, as specified in paragraphs (k) and (m) of this AD, constitutes terminating action for the inspection requirements of ALI task 531110, for those holes for that airplane.

(p) No Reporting Requirement

Although Airbus Service Bulletin A320–53–1286, Revision 01, dated December 22, 2015, specifies to submit certain information to the manufacturer, and specifies that action as "RC" (Required for Compliance), this AD does not include that requirement.

(q) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) and (h) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–53–1286, dated June 29, 2015.

(r) Service Information Exceptions

Where Subtasks 531295–960–001–001 and 532195–960–002–001 of Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015, refer to actions when an existing hole diameter is "more than or equal to the minimum starting hole diameter," this AD requires applicable actions in cases where the hole diameter is "more than or equal to the maximum starting hole diameter."

(s) Other FAA AD Provisions

The following provisions also apply to this AD:

- (1) Alternative Methods of Compliance (AMOCs): The Manager, International Section, Transport Standards Branch, 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 Section, send it to the attention of the person identified in paragraph (t)(2) of this AD. 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.
- (2) Contacting the Manufacturer: 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 Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.
- (3) Required for Compliance (RC): Except as required by paragraphs (h)(1) and (p) of this AD: If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests

that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(t) Related Information

- (1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016–0139, dated July 14, 2016, 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–2017–1093.
- (2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.
- (3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (u)(3) and (u)(4) of this AD.

(u) 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 this AD specifies otherwise.
- (i) Airbus Service Bulletin A320–53–1286, Revision 01, dated December 22, 2015.
- (ii) Airbus Service Bulletin A320–53–1295, including Appendixes 01 and 02, dated June 29, 2015.
- (3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 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.
- (4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.
- (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 Des Moines, Washington, on June 29, 2018.

Jeffrey E. Duven,

 $\label{lem:constraint} \begin{cal}Director, System\ Oversight\ Division,\ Aircraft\ Certification\ Service.\end{cal}$

[FR Doc. 2018–14687 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 61, 67, 91, and 120

Settlement Policy for Commercial Pilots in Drug and Alcohol Testing Cases

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notification of enforcement policy.

SUMMARY: The FAA is adopting a procedure for prompt settlement agreements between the FAA and commercial pilots who have: Received a verified positive result for a Department of Transportation (DOT)-required drug test; received a DOT-required alcohol test result of .04 or above alcohol concentration; refused to submit to a DOT-required drug or alcohol test in violation of FAA regulations; or acted or attempted to act as a crewmember of an aircraft in commercial operations in violation of specified FAA regulations under this policy that proscribe the use, being under the influence or affects, or while have proscribed levels of alcohol or drugs. The settlement agreement procedures in this notification are generally available to pilots who, but for the disqualifying DOT drug or alcohol test result, refusal to submit to a DOT test, or violation of the specified alcohol- and drug-related FAA regulations prohibiting acting or attempting to act as a crewmember, would be qualified for a pilot certificate and who are first-time violators of these drug or alcohol provisions.

DATES: The enforcement policy is effective October 1, 2018.

FOR FURTHER INFORMATION CONTACT:

James Barry, Manager, Policy/Audit/ Evaluation, Enforcement Division, AGC-300, Federal Aviation Administration. 800 Independence Avenue SW, Washington, DC 20591; telephone (202) 267-8198; james.barry@ faa.gov.

SUPPLEMENTARY INFORMATION:

Background

A commercial pilot who receives a disqualifying DOT drug or alcohol test result, refuses a DOT drug or alcohol test, or violates § 91.17(a)(1) through (4) is subject to the revocation of airman certificates issued under 14 CFR part 61 and airman medical certificates issued under 14 CFR part 67. Under 14 CFR 61.13(d)(2), unless otherwise authorized by the Administrator, a person whose pilot, flight instructor, or ground instructor certificate has been revoked

may not apply for any certificate, rating, or authorization for one year after the date the FAA issued the revocation order.

Many commercial pilots who receive a disqualifying DOT drug or alcohol test result, refuse a DOT drug or alcohol test, or violate § 91.17(a)(1) through (4) promptly enter into the Human Intervention Motivation Study ("HIMS") program, which is a substance recovery program for such pilots. 1 If a pilot undergoes evaluation, and successfully completes appropriate treatment and remains under comprehensive continuing care in accordance with the HIMS program, the pilot may become eligible for an authorization for special issuance of an airman medical certificate ("special issuance") well before the completion of an FAA investigation into the matter, initiation of legal enforcement action based on the investigation, and passage of the time period specified in 14 CFR

61.13(d)(2).2

Indeed, following the discovery of a disqualifying DOT drug or alcohol test result, DOT drug or alcohol test refusal, or violation of 14 CFR 91.17(a)(1) through (4), the FAA Office of Aerospace Medicine, Drug Abatement Division ("AAM-800") investigates the apparent violation, which includes interviews and the collection of evidence, and develops an enforcement investigative report ("EIR"), which is subject to AAM-800 management review. If AAM-800 management deems the EIR sufficient, it transmits the EIR to the Office of the Chief Counsel's Enforcement Division ("AGC-300") for additional review to ensure, among other things, evidentiary sufficiency and compliance with law and policy. Consistent with FAA policy, AGC-300 issues an order revoking pilot and airman medical certificates only after the thorough review necessary to ensure that legal enforcement action involving

the revocation of certificates is appropriate. Although the FAA normally issues emergency orders of revocation for the types of drug or alcohol violations discussed in this notification, the FAA necessarily takes the appropriate amount of time to ensure that the issuance of the order is reasonable and supportable. Accordingly, the period of time between the FAA's discovery of a drug or alcohol violation and the issuance of a certificate action can be lengthy. Further, the additional time period specified in 14 CFR 61.13(d)(2) adds up to a year after the issuance of an order of revocation. During the period from the discovery of the violation to the expiration of the time period specified in 14 CFR 61.13(d)(2), a pilot may have long successfully completed recovery steps necessary to be found qualified for a special issuance.

Policy Statement

Under the new prompt settlement procedure, the FAA will send notification to commercial pilots who receive a disqualifying DOT drug or alcohol test result, refuse a DOT drug or alcohol test, or violate § 91.17(a)(1) through (4) in commercial operations. The notification will inform the pilot that he or she may contact AAM-800 within ten days of receipt of the notice to request consideration for a prompt settlement of the legal enforcement action. The FAA will send the notification soon after it discovers the violation.

If the pilot requests to be considered for the new settlement procedure, the FAA will determine whether the pilot is eligible for the process. The procedure is not available where there is a question about a pilot's qualification to hold a certificate other than that presented by the disqualifying DOT drug or alcohol test result, refusal to submit to a DOT test, or violation of § 91.17(a)(1) through (4), or where the pilot is not a first-time violator of these drug or alcohol testing provisions. If the FAA deems application of the prompt settlement procedure is appropriate, AGC-300 enforcement counsel will provide the pilot, or his or her legal representative, a formal agreement that sets forth the conditions for prompt settlement. The terms of the settlement agreement will normally include the following provisions.

(1) The settlement agreement must be executed by the parties within ten days after the FAA transmits the agreement to

(2) The FAA will issue an emergency order revoking all certificates the pilot holds that were issued under 14 CFR

¹ A pilot is not permitted to fly commercially after receiving a disqualifying DOT drug or alcohol test result or having refused a DOT drug or alcohol test unless the pilot completes a substance abuse professional (SAP) evaluation and undergoes referral for education/treatment and return-to-duty testing. Further, under 14 CFR 61.53(a), a pilot is prohibited from acting as a required flight crew member when he or she knows, or has reason to know, that he or she has a disqualifying medical condition, which includes substance abuse or dependence under 14 CFR part 67.

² Under 14 CFR 67.401(a), the Federal Air Surgeon has discretion to grant a special issuance to a pilot who does not meet the requirement for unrestricted airman medical certification if the airman can show to the satisfaction of the Federal Air Surgeon that the duties authorized by the class of medical certificate applied for can be performed without endangering public safety during the period in which the authorization would be in

parts 61 and 67 immediately upon receiving the fully executed settlement agreement.

- (3) The emergency order of revocation will: (i) Require the immediate surrender of all certificates the pilot holds that were issued under 14 CFR parts 61 and 67 to enforcement counsel; (ii) notify the pilot that the failure to immediately surrender these certificates could subject the pilot to further legal enforcement action, including a civil penalty; and (iii) inform the pilot that the FAA will not accept an application for a new certificate issued under 14 CFR part 61 for a period of a year from the date of the issuance of the emergency order of revocation.
- (4) The pilot will waive all appeal rights from the emergency order of revocation.
- (5) The parties will agree to bear their own costs and attorney fees, if any, in connection with the matter.
- (6) The pilot will agree to not initiate any litigation before any court, tribunal, or administrative entity concerning any costs or attorney fees, including applications under the Equal Access to Justice Act, incurred as a result of the above-referenced matter.
- (7) The pilot will agree to waive any and all causes of action against the FAA and its current and/or former officials and employees relating to the above-referenced matter.

This procedure is expected to allow pilots who have established qualifications to hold a new 14 CFR part 61 certificate, and have met the requirements under 14 CFR part 67 for a special issuance consistent with participation in the HIMS program, to more quickly assume commercial flight crewmember duties. Indeed, it should allow pilots to apply for a new pilot certificate closer in time to a determination that the pilot is eligible for a special issuance (following timely evaluation, treatment, and continuing comprehensive care in accordance with the HIMS program). Further, the added predictability of this process should allow pilots who have received a disqualifying DOT drug or alcohol test result, refused to submit to a DOT test, or violated § 91.17(a)(1) through (4) to focus effort and energy on the treatment and recovery process, and allow both the pilot and FAA to better allocate limited resources.

Issued in Washington, DC, on July 12, 2018.

Naomi Tsuda,

Assistant Chief Counsel for Enforcement. [FR Doc. 2018–15352 Filed 7–18–18; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2018-0676]

Drawbridge Operation Regulation; Willamette River at Portland, OR

AGENCY: Coast Guard, DHS. **ACTION:** Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Hawthorne Bridge across the Willamette River, mile 13.1, at Portland, OR. The deviation is necessary to accommodate a filming event for a movie. This deviation authorizes the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective from 6 p.m. on September 1, 2018, to 12:01 a.m. on September 2, 2018.

ADDRESSES: The docket for this deviation, USCG-2018-0676 is available at 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 deviation.

FOR FURTHER INFORMATION CONTACT: If

you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206–220–7282, email d13-pf-d13bridges@uscg.mil.

SUPPLEMENTARY INFORMATION:

Multnomah County, the bridge owner, has requested a temporary deviation from the operating schedule for the Hawthorne Bridge across the Willamette River, mile 13.1, at Portland, OR. The requested deviation is to accommodate a filming event for a movie. To facilitate this event, the draw of the subject bridge will be allowed to remain in the closedto-navigation position, and need not open to marine traffic from 6 p.m. on September 1, 2018, to 12:01 a.m. on September 2, 2018. The Hawthorne Bridge provides a vertical clearance of 49 feet in the closed-to-navigation position referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule is in 33 CFR 117.897(c)(3)(v). Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft. The Coast Guard requested objections to this deviation from local mariners via the Local Notice

Mariners, and email. No objections were submitted to the Coast Guard.

Vessels able to pass through the bridge in the closed-to-navigation position may do so at any time. The bridge will be able to open for emergencies, and there is no immediate alternate route for vessels to pass. The Coast Guard will inform the users of the waterway, through our Local and Broadcast Notices to Mariners, of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 13, 2018.

Steven M. Fischer,

Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2018–15434 Filed 7–18–18; 8:45 am] **BILLING CODE 9110–04–P**

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2018-0521]

Safety Zone; Southern California Annual Firework Events for the San Diego Captain of the Port Zone

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a safety zone for the San Diego, CA POPS Fireworks Display on the waters of San Diego Bay, CA on specific evenings from June 28, 2018 to September 2, 2018. This safety zone is necessary to provide for the safety of the participants, spectators, official vessels of the events, and general users of the waterway. Our regulation for the Southern California Annual Firework Events for the San Diego Captain of the Port Zone identifies the regulated area for the events. During the enforcement period, no spectators shall anchor, block, loiter in, or impede the transit of official patrol vessels in the regulated area without the approval of the Captain of the Port, or designated representative.

DATES: The regulations in 33 CFR 165.1123 will be enforced from 9:00

p.m. through 10:00 p.m. on July 27 and July 28, August 3, August 6 and August 7, August 11, August 17 and August 18, August 24 and August 25, and August 30 through September 2, 2018 for Item 1 in Table 1 of 33 CFR 165.1123.

FOR FURTHER INFORMATION CONTACT: If you have questions on this publication, call or email LTJG Briana Biagas, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, email D11MarineEventsSD@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the regulations in 33 CFR 165.1123 for a safety zone on the waters of San Diego Bay, CA for the San Diego, CA POPS Fireworks Display in 33 CFR 165.1123, Table 1, Item 1 of that section, from 9:00 p.m. through 10:00 p.m. on specific evenings from June 28, 2018 to September 2, 2018. This action is being taken to provide for the safety of life on navigable waterways during the fireworks events. Our regulation for Southern California Annual Firework Events for the San Diego Captain of the Port Zone identifies the regulated areas for the events. Under the provisions of 33 CFR 165.1123, a vessel may not enter the regulated area, unless it receives permission from the Captain of the Port, or his designated representative. Spectator vessels may safely transit outside the regulated area but may not anchor, block, loiter, or impede the transit of participants or official patrol vessels. The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation.

This document is issued under authority of 33 CFR 165.1123 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and local advertising by the event sponsor.

If the Captain of the Port or his designated representative determines that the regulated area need not be enforced for the full duration stated on this document, he or she may use a Broadcast Notice to Mariners or other communications coordinated with the event sponsor to grant general permission to enter the regulated area.

Dated: June 27, 2018.

J.R. Buzzella,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2018-15440 Filed 7-18-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2018-0578]

RIN 1625-AA00

Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez; Valdez, AK; Correction

AGENCY: Coast Guard, DHS. **ACTION:** Final rule; correction.

SUMMARY: The Coast Guard is correcting a final rule that appeared in the **Federal Register** on July 12, 2018. The Coast Guard issued a final rule republishing its 2014 rule that established a permanent safety zone on the navigable waters of Port Valdez within a 200-yard radius of the Alaska Marine Highway System (AMHS) Port Valdez Ferry Terminal.

DATES: Effective July 19, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG-2018-0578 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email LTJG, Carlos M. Quintero, MSU Valdez, U.S. Coast Guard; telephone 907–835–7209, email Carlos.M.Quintero@uscg.mil.

SUPPLEMENTARY INFORMATION: In FR 2018–14863 appearing on page 32208 in the **Federal Register** of Thursday, July 12, 2018, the following correction is made:

§165.1712a [Corrected]

■ 1. On page 32209, in the second column, in part 165, in amendment 2, the section heading "§ 165.1712a Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez, Valdez, AK." is corrected to read "§ 165.1714 Safety Zone; Alaska Marine Highway System Port Valdez Ferry Terminal, Port Valdez, Valdez, AK.".

Date: July 16, 2018.

Katia Kroutil,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2018–15438 Filed 7–18–18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2017-1095]

RIN 1625-AA11

Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, II

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard Ninth District Commander is amending the navigational and operational restrictions of the Regulated Navigation Area (RNA) on the Chicago Sanitary and Ship Canal (CSSC) near Romeoville, Illinois, and removing the redundant Safety Zone currently in place. The purpose of this amendment is to improve safety and clarify regulations for vessels transiting the navigable waters located adjacent to and over the U.S. Army Corps of Engineers' Aquatic Nuisance Species electric dispersal barrier system (EDBS).

DATES: This rule is effective August 20, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG-2017-1095 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rulemaking, call or email Lieutenant John Ramos, Marine Safety Unit Chicago, U.S. Coast Guard; telephone (630) 986–2131, email John.E.Ramos@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
CSSC Chicago Sanitary and Ship Canal
DHS Department of Homeland Security
EDBS Electric Dispersal Barrier System
E.O. Executive order
FR Federal Register
NPRM Notice of proposed rulemaking
Pub. L. Public Law
RNA Regulated Navigation Area
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The purpose of this rule is to eliminate a redundant safety zone and remove several requirements from a Regulated Navigation Area that are no longer necessary. There currently exists, in 33 CFR 165.923, certain navigational, environmental, and operational restrictions on all vessels transiting the navigable waters located adjacent to and over the U.S. Army Corps of Engineers' Aquatic Nuisance Species electric dispersal fish barrier. Title 33 CFR 165.923(a)(1) establishes a safety zone in the CSSC from mile marker 296.1 to mile marker 296.7. Additionally, 33 CFR 165.923(b)(1) establishes a regulated navigation area from mile marker 295.5 to mile marker 297.2. There also exists, in 33 CFR 165.930, a safety zone from mile marker 286.0 to mile marker 333.3 that includes the totality of the safety zone in 33 CFR 165.923(a)(1), rendering it redundant.

In 2013, the U.S. Coast Guard Research and Development Center completed a marine safety risk assessment for the waters of the CSSC in the vicinity of the Aquatic Nuisance Species EDBS near Romeoville, Illinois. The overarching goal of the risk assessment was to determine the adequacy of present risk mitigation strategies and, if necessary, recommend alternatives to the present strategies. The report generated at the conclusion of the risk assessment noted confusion among waterway users regarding the boundaries and requirements for the safety zone and RNA outlined in 33 CFR 165.923. The report also identified certain requirements still in effect, which had basis in the existing rule, that have since changed over the period of the rule and no longer apply.

On January 30, 2018, the Coast Guard published a notice of proposed rulemaking (NPRM) titled "Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, IL" (USCG-2017–1095), 83 FR 4171. The NPRM discussed the need for the rule and invited the public to comment on the proposed regulatory action. During the comment period that ended April 30, 2018, we received two comments. One comment was not relevant to the proposed rule. The second comment, from the American Waterways Operators, stated support for the proposed RNA amendments.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under 33 U.S.C. 1231.

The purpose of this rulemaking is to address recommended amendments to the regulations based on the aforementioned report's conclusions and recommendations. The changes are intended to improve safety, reduce confusion and eliminate unnecessary burden to vessels transiting the safety zone and RNA of the CSSC in the

vicinity of the EDBS near Romeoville, Illinois.

IV. Discussion of Comments, Changes, and the Rule

As noted above, we received two comments on our NPRM published January 30, 2018. Other than some minor stylistic changes, there are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

The purpose of the safety zone delineated in § 165.923(a)(1) is to inhibit the potential transfer of live Silver or Asian carp, viable eggs or gametes into the waterway north of the electric barrier. To serve this purpose, the safety zone requirements outlined in 33 CFR 165.923(a)(2) restrict vessels transiting with non-potable water on board if they intend to release that water in any form within or on the other side of the safety zone. A larger safety zone, described at 33 CFR 165.930(a)(2), also encompasses this same area. That safety zone, however, does not contain regulations for the transit of non-potable water.

The Coast Guard will eliminate the CSSC safety zone outlined in 33 CFR 165.923(a)(1). This revision eliminates redundancy in regulations by using the larger safety zone delineated in 33 CFR 165.930(a)(2) to regulate the CSSC. The requirements in 33 CFR 165.923(a)(2) for the transit of non-potable water will be preserved, but incorporated into the CSSC's RNA regulations in what is now 33 CFR 165.923(b)(2). Therefore, 33 CFR 165.923(b) will become 33 CFR 165.923(a) with the elimination of the safety zone. The following paragraphs describe additional changes made to the RNA regulations.

The Coast Guard will remove the RNA's bow boat requirement in 33 CFR 165.923(b)(2)(ii)(C). The RNA currently requires that all up-bound and downbound tows that consist of barges carrying flammable liquid cargoes (Grade A through C, flashpoint below 140 degrees Fahrenheit, or heated to within 15 degrees Fahrenheit of flash point) engage the services of a bow boat at all times until the entire tow is clear of the RNA. The original bow boat requirement was intended to reduce the possibility of a spark-induced event due to allision between a barge carrying flammable liquid cargo and barges at the Will County Generating Station Coal Wharf (RDB MM 296.0) while the facility conducted coal loading and barge fleeting. At times barge fleets were three-wide (approximately 105 feet), extended into the 160-wide cut, less than 500 feet downstream of Barrier II-A. Since barge loading and fleeting

ceased in September 2012, the basis for this requirement no longer exists.

The Coast Guard is modifying the requirement in 33 CFR 165.923(b)(2)(ii)(E) that require commercial tows be made up with only wire rope to ensure electrical connectivity between all segments of the tow. The purpose of this requirement is to ensure electrical connectivity between all segments of the tow to prevent arcing while transiting the electric barrier and to prevent high contact potentials between vessels in the tow. However, the Coast Guard recognizes that adequate means of securing a tow configuration are not exclusive to the use of wire rope and towboats frequently use high-tensile strength aramid, high-modulus polyethylene, or composite fiber ropes ("soft-lines") as wing-wires or facewires, and occasionally as barge lashings. Government observers have seen towboats use a single, wire-rope from barge winch to towboat h-bitt, thus providing adequate electrical connectivity, if sufficiently taut, and contacting bare-metal surfaces. The Coast Guard thus will continue to require that commercial tows transiting the RNA ensure the maintenance of electrical connectivity between all segments of the tow through use of wire rope, but allow use of soft lines to be used in addition to secure a tow. To account for use of soft-lines, the Coast Guard proposed to eliminate the requirement that a tow exclusively use wire rope, by removing the words "with only" from the paragraph and allowing an appropriate alternative.

Finally, the Coast Guard will add a requirement to the RNA regulations that all vessels transit the RNA at a "nowake" speed. Currently, the RNA does not provide a maximum safe speed for vessels transiting the RNA. Throughout the course of the marine risk assessment, the project team ascertained that the largest marine safety risk is electric shock to a person in the water. Video recordings and shore-observer accounts indicate that many, smaller recreational vessels transit the EDBS at a speed that generates significant wake. Also, light-boat transits drag a wake that causes surging of barges moored to the loading facility just north of the pipeline arch. A no-wake zone will reduce this risk not only to persons aboard vessels, but also to persons working ashore alongside the RNA.

The aforementioned changes to the RNA regulations will require a slight reordering of what is now 33 CFR 165.923(b)(2)(ii)(A) through (K). With the removal of the safety zone, these regulations will be found in 33 CFR

165.923(a). The removal of the bow boat requirement in 33 CFR 165.923(b)(2)(ii)(C) will cause the other requirements to move up a letter, becoming the new 33 CFR 165.923(a)(2)(ii)(C) through (J). The "no wake" requirement will then become the new 33 CFR 165.923(a)(2)(ii)(K) and the requirements for the transit of nonpotable water will be added in a new 33 CFR 165.923(a)(2)(ii)(L).

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

The rule updates an already existing rule. It adds minor changes to that already existing rule. These changes involve the elimination of a redundant safety zone, the removal of several requirements from a Regulated Navigational Area that are no longer necessary, and adds a "no wake" requirement to the safety zone. Each of these is discussed in greater depth below. We anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. A summary of the reasoning for this is provided below. For a more thorough explanation of the reasoning the reader is advised to refer to the NPRM on this rule that was published in the Federal Register on January 30, 2018.

This final rule eliminates the CSSC safety zone outlined in 33 CFR 165.923(a)(1). This will reduce

redundancy in regulations as the CSSC safety zone is already regulated in an equivalent manner by the larger safety zone delineated in 33 CFR 165.930(a)(2). Hence it is expected that there will be no cost impact associated with this change. In addition, it will reduce confusion and uncertainty that the public may face. The American Waterways Operators (AWO), in a comment made to the docket, agrees with this assessment. The AWO, in its comment, stated "removing the redundant safety zone will decrease confusion for vessels operators in the transiting area".

A second change made by this rule is the incorporation of the requirements for the transit of non-potable water, contained in 33 CFR 165.930(a)(2), into 33 CFR 165.923(b)(2). As this is only a move of the water transit requirements from one section of the CFR to another part of the CFR no costs experienced. In addition, the public will face less uncertainty due to the reduction of overlapping regulatory requirements.

A third change the rule will make will be the elimination of the RNA's bow boat requirement, contained in 33 CFR 165.923(b)(2)(ii)(C). The RNA currently requires that all up and down bound tows that consist of barges carrying flammable liquid cargoes engage the services of a bow boat at all times until the entire tow is clear of the RNA.² The purpose of this requirement of 33 CFR 165.923(b)(2)(ii)(C) was to reduce the possibility of a spark-induced event due to allision between a barge carrying flammable liquid cargo and barges at the Will County Generating Station Coal Warf (RDB MM 296.0) while the facility conducted coal loading and barge fleeting. As barge loading and fleeting at this facility stopped in September 2012, the basis of this requirement no longer exists. Hence there are expected to be reduced costs, for the regulated public, associated with the removal of this requirement.3

A fourth change involves the modification of the requirement in 33 CFR 165.923(b)(2)(ii)(E) relating to wire ropes used in commercial tows. Currently this requires that only wire rope be used in commercial tows. The purpose is to ensure electrical connectivity between all segments of the tow during the duration of the tow. This reduces the possibility of an accident stemming from the loss of power to any segment of the tow. However, the Coast Guard recognizes that there are hightensile strength aramid, high-modulus polyethylene or composite fiber ropes ("soft-lines") that also provide adequate electrical connectivity. The modification hence expands the ability of in-scope vessels to use these forms of ropes as well as wire ropes. This, in turn, provides vessel owners greater flexibility in terms of the type of ropes they use at with no additional cost being imposed by the regulation.

Ĺastly, tȟe Coasť Guard proposed to add a requirement to the RNA regulations that all vessels transit the RNA at a "no-wake" speed. The new "no-wake" requirement is contained in the new 33 CFR 165.923(a)(2)(ii)(K). Currently, the RNA does not provide a maximum safe speed for vessels transiting the RNA. This "no-wake" requirement is expected to reduce the danger posed by electrocution to persons on board vessels or falling overboard as well as to persons walking alongside the RNA on shore.4 Wakes currently caused by vessels exceeding a "no-wake" speed carry this danger because, in the RNA, the Aquatic Nuisance Species electric dispersal fish barrier generates a highly charged electrical field.

The Coast Guard received two comments in response to the NPRM published with respect to this final rule. One comment was not relevant to the proposed rule. The second comment,

¹Public comment received from the American Waterways Operators in response to the NPRM on this rule, dated April 30, 2018. A copy of this can be found in the docket for this rule.

² For a detailed list of the flammable liquid cargoes covered, please reference the NPRM for this rule.

³ The AWO, in a letter in response to the NPRM for this final rulemaking (dated April 30, 2018 and contained in the docket for the NPRM), agreed with this conclusion. It stated "[the] AWO greatly appreciates the removal of the bow boat requirement for all tows moving flammable liquid cargoes. . . . These added operational costs have been a burden to our customers, increasing cost to consumers. The Coast Guard's proposal to eliminate the bow boat requirement will benefit the economic well-being of the towing industry, its customers, and the national economy".

⁴ The AWO, in a letter dated April 30, 2018, in response to the NPRM for this final rule (a copy can be found in the docket accompanying this NPRM) agrees with the Coast Guard's assessment. The AWO writes: "AWO applauds applauds the Coast Guard's proposal to require all vessels to transit the RNA at a "no-wake" speed to help mitigate many of the safety risks associated with transiting the Electric Dispersal Barrier System (EDBS). Located near Romeoville, Illinois, the EDBS is the only location the Coast Guard will not rescue individuals who fall overboard due to the unsafe conditions for its highly-trained personnel. Studies conducted by the U.S. Navy confirmed a 50% fatality rate if an individual falls into the electrified water. Given the extreme dangers associated with the EDBS, towboat operators are extremely cautious when transiting the RNA. Unfortunately, towboat operators have encountered recreational vessels operating at speeds inside the RNA that pose serious safety risks to surrounding vessels and crew. By introducing a no-wake speed, all vessels will be required to transit the area in a safe and responsible manner."

from the American Waterways
Operators, stated that it agreed with a
number of the proposed RNA
amendments made in the NPRM (and
included in this final rule). The AWO's
comments in favor of many of the
proposed changes have already been
mentioned above. The AWO had no
negative comments in response to any of
the proposed RNA amendments.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601-612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 received no comments from the Small Business Administration on this rulemaking. 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.

The revision of the safety zone and RNA will not have a significant economic impact on a substantial number of small entities because the proposed revision imposes minor additional requirements on industry; and provides clarity to preexisting requirements by removing redundancies. This rule, by removing the bow boat requirement due to the ceased barge loading and fleeting operations, is expected to reduce regulated costs.

The increased flexibility provided to small entity vessel owners and operators by permitting them to use, in addition to wire ropes, high-tensile strength aramid, high-modulus polyethylene or composite fiber ropes ("soft-lines") is also expected to have no cost impact on them while simultaneously providing them with greater flexibility on the types of wires they can use.

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.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) nor will it modify an existing collection.

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves

revisions of the safety zone and RNA that provide clarity to preexisting requirements. Normally such actions are categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. Paragraph L60 pertains to establishing, disestablishing, or changing Regulated Navigation Areas and Safety Zones. A Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES.

G. 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.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 165.923 to read as follows:

§ 165.923 Regulated Navigation Area, Chicago Sanitary and Ship Canal, Romeoville, IL.

- (a) Regulated navigation area and regulations. (1) The following is a regulated navigation area (RNA): All waters of the Chicago Sanitary and Ship Canal, Romeoville, IL located between mile marker 295.5 and mile marker 297.2.
- (2)(i) The general regulations contained in § 165.13 apply.
- (ii) Vessels that comply with the following restrictions are permitted to transit the RNA:
- (A) Vessels must be greater than 20 feet in length.
- (B) Vessels must not be a personal or human powered watercraft (*i.e.*, jet skis, waver runners, kayaks, row boats, etc.).
- (C) Vessels engaged in commercial service, as defined in 46 U.S.C. 2101(5), may not pass (meet or overtake) in the

RNA and must make a SECURITÉ call when approaching the RNA to announce intentions and work out passing arrangements.

(D) Commercial tows transiting the RNA must use wire rope or appropriate alternatives to ensure electrical connectivity between all segments of the

(E) All vessels are prohibited from loitering in the RNA.

- (F) Vessels may enter the RNA for the sole purpose of transiting to the other side and must maintain headway throughout the transit. All vessels and persons are prohibited from dredging, laying cable, dragging, fishing, conducting salvage operations, or any other activity, which could disturb the bottom of the RNA.
- (G) Except for law enforcement and emergency response personnel, all personnel on vessels transiting the RNA should remain inside the cabin, or as inboard as practicable. If personnel must be on open decks, they must wear a Coast Guard approved personal flotation device.
- (H) Vessels may not moor or lay up on the right or left descending banks of the RNA.
- (I) Towboats may not make or break tows if any portion of the towboat or tow is located in the RNA.
- (J) Persons onboard any vessel transiting the RNA in accordance with this rule or otherwise are advised they do so at their own risk.
- (K) All vessels transiting the RNA are required to transit at a no wake speed but still maintain bare steerageway.
- (L)(1) All vessels are prohibited from transiting the restricted navigation area with any non-potable water on board if they intend to release that water in any form within, or on the other side of the restricted navigation area. Non-potable water includes, but is not limited to, any water taken on board to control or maintain trim, draft, stability, or stresses of the vessel. Likewise, it includes any water taken on board due to free communication between the hull of the vessel and exterior water. Potable water is water treated and stored aboard the vessel that is suitable for human consumption.
- (2) Vessels with non-potable water on board are permitted to transit the restricted navigation area if they have taken steps to prevent the release, in any form, of that water in or on the other side of the restricted navigation area. Alternatively, vessels with non-potable

water on board are permitted to transit the restricted navigation area if they have plans to dispose of the water in a biologically sound manner.

(3) Vessels with non-potable water aboard that intend to discharge on the other side of the restricted navigation area must contact the Coast Guard's Ninth District Commander or his or her designated representatives prior to transit and obtain permission to transit and discharge. Examples of discharges that may be approved include plans to dispose of the water in a biologically sound manner or demonstrate through testing that the non-potable water does not contain potential live Silver or Asian carp, viable eggs, or gametes.

(4) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within this safety zone by vessels with non-potable water on board is prohibited unless authorized by the Coast Guard's Ninth District Commander, his or her designated representatives, or an onscene representative.

(5) The Captain of the Port, Lake Michigan, may further designate an "onscene" representative. The Captain of the Port, Lake Michigan, or the on-scene representative may be contacted via VHF-FM radio Channel 16 or through the Coast Guard Lake Michigan Command Center at (414) 747-7182.

(b) *Definitions*. The following definitions apply to this section:

Designated representative means the Captain of the Port Lake Michigan and Commanding Officer, Marine Safety Unit Chicago.

On-scene representative means any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Lake Michigan, to act on his or her behalf. The on-scene representative of the Captain of the Port, Lake Michigan, will be aboard a Coast Guard, Coast Guard Auxiliary, or other designated vessel or will be onshore and will communicate with vessels via VHF–FM radio or loudhailer.

Vessel means every description of watercraft of other artificial contrivance used, or capable or being used, as a means of transportation on water. This definition includes, but is not limited to, barges.

(c) Compliance. All persons and vessels must comply with this section and any additional instructions or orders of the Coast Guard's Ninth District Commander or his or her

designated representatives. Any person on board any vessel transiting this RNA in accordance with this rule or otherwise does so at his or her own risk.

(d) Waiver. For any vessel, the Coast Guard's Ninth District Commander or his or her designated representatives may waive any of the requirements of this section, upon finding that operational conditions or other circumstances are such that application of this section is unnecessary or impractical for the purposes of vessel and mariner safety.

Dated: July 16, 2018.

J.M. Nunan,

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

[FR Doc. 2018-15428 Filed 7-18-18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2018-0524]

Safety Zone; Swim Event in Captain of the Port New York Zone

AGENCY: Coast Guard, DHS. **ACTION:** Notice of enforcement of

regulation.

SUMMARY: The Coast Guard will enforce a safety zone within the Captain of the Port New York Zone on the specified date and times provided below. This action is necessary to ensure the safety of vessels, spectators and participants from hazards associated with a swim event. During the enforcement period, no person or vessel may enter the safety zones without permission of the Captain of the Port (COTP).

DATES: The regulation for the safety zone described in 33 CFR 165.160 will be enforced on the date and times listed in the table below.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Petty Officer First Class Ronald Sampert U.S. Coast Guard; telephone 718–354–4197, email ronald.j.sampert@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the safety zone listed in Table 2 of 33 CFR 165.160 on the specified date and time as indicated in the table below.

TABLE

Swim Across America Safety Zone 33 CFR 165.160 (3.1)

- Location: Participants will swim between Glenn Cove Larchmont, New York and an area of Hempstead Harbor between Glen Cove and the vicinity of Umbrella Point. This Safety Zone includes all waters within a 100-yard radius of each participating swim-
- Date: July 28, 2018.
- Time: 5:30 a.m.-12:00 p.m.

Under the provisions of 33 CFR 165.160, vessels may not enter the safety zone unless given permission from the COTP or a designated representative. Spectator vessels may transit outside the safety zones but may not anchor, block, loiter in, or impede the transit of other vessels. The Coast Guard may be assisted by other Federal, State, or local law enforcement agencies in enforcing this regulation.

This document is issued under authority of 33 CFR 165.160(a) and 5 U.S.C. 552(a). In addition to this notice of enforcement in the Federal Register, the Coast Guard will provide mariners with advanced notification of enforcement periods via the Local Notice to Mariners and marine information broadcasts.

If the COTP determines that a safety zone need not be enforced for the full duration stated in this document, a Broadcast Notice to Mariners may be used to grant general permission to enter the safety zone.

Dated: June 28, 2018.

J.P. Tama,

Captain, U.S. Coast Guard, Captain of the Port New York.

[FR Doc. 2018-15441 Filed 7-18-18; 8:45 am] BILLING CODE 9110-04-P

DEPARTMENT OF EDUCATION

34 CFR Part 685

[Docket ID ED-2017-OPE-0112]

RIN 1840-AD28

Student Assistance General Provisions, Federal Perkins Loan Program, Federal Family Education Loan Program, William D. Ford Federal Direct Loan Program, and Teacher **Education Assistance for College and Higher Education Grant Program;** Corrections

AGENCY: Office of Postsecondary Education, Department of Education. **ACTION:** Final rule; correcting amendments.

SUMMARY: In the **Federal Register** of February 14, 2018, the Department of Education (Department) published a

final rule (the delay rule) delaying, until July 1, 2019, the effective date of selected provisions of the final regulations entitled Student Assistance General Provisions, Federal Perkins Loan Program, Federal Family Education Loan Program, William D. Ford Federal Direct Loan Program, and Teacher Education Assistance for College and Higher Education Grant Program (the 2016 final regulations), published in the **Federal Register** on November 1, 2016. This rule inadvertently omitted regulations from the list in the DATES section of regulations for which the effective date is delayed. This document removes the regulations that we intended to delay from the text of the Code of Federal Regulations and specifies July 1, 2019 as their effective date.

DATES: This rule is effective July 19, 2018 except for amendatory instruction 3 which is effective July 1, 2019.

FOR FURTHER INFORMATION CONTACT:

Annmarie Weisman, U.S. Department of Education, 400 Maryland Avenue SW, Mail Stop 294–20, Washington, DC 20202-6244. Telephone: (202) 453-6712. Email: annmarie.weisman@ ed.gov.

If you use a telecommunications device for the deaf or a text telephone, call the Federal Relay Service, toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION: In the delay rule (83 FR 6458), the list of regulations in the DATES section in the first column on page 6459, for which the effective date is delayed until July 1, 2019, inadvertently excluded § 685.300(b)(11), (b)(12), and (d) through (i). Those regulations were properly included in the list of regulations for which the effective date is delayed in the body of the document (in the third column of page 6459) and discussed elsewhere in the document. However, to effectuate this correction and restore the Code of Federal Regulations to properly reflect the delay, we are publishing amendatory language that will remove these provisions.

Waiver of Proposed Rulemaking

In accordance with the Administrative Procedure Act, 5 U.S.C. 553, it is the Secretary's practice to offer interested parties the opportunity to comment on proposed regulations. However, the actions in this document are merely to correct a technical error. and thus, the Secretary has determined that publication of a proposed rule is unnecessary under 5 U.S.C. 553(b)(B).

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the contact person listed under FOR FURTHER INFORMATION CONTACT.

Electronic Access to This Document: The official version of this document is the document published in the Federal Register. You may access the official edition of the Federal Register and the Code of Federal Regulations via the Federal Digital System at: www.gpo.gov/ fdsvs. At this site you can view this document, as well as all other documents of this Department published in the Federal Register, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the Federal Register by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

List of Subjects in 34 CFR Part 685

Administrative practice and procedure, Colleges and universities, Loan programs—education, Reporting and recordkeeping requirements, Student aid, Vocational education.

Dated: July 12, 2018.

Betsy DeVos,

Secretary of Education.

For the reasons discussed in the preamble, the Secretary of Education amends part 685 of title 34 of the Code of Federal Regulations as follows:

PART 685—WILLIAM D. FORD FEDERAL DIRECT LOAN PROGRAM

■ 1. The authority citation for part 685 continues to read as follows:

Authority: 20 U.S.C. 1070g, 1087a, et seq., unless otherwise noted.

§ 685.300 [Amended]

- 2. Effective July 19, 2018, § 685.300 is amended by:
- a. Removing paragraph (b)(11) and redesignating paragraph (b)(12) as paragraph (b)(11).
- b. Řemoving paragraphs (d) through (i).
- 3. Effective July 1, 2019, § 685.300 is amended by:
- a. Redesignating paragraph (b)(11) as paragraph (b)(12).
- b. Adding a new paragraph (b)(11).
- c. Adding paragraphs (d) through (i). The additions read as follows:

§ 685.300 Agreements between an eligible school and the Secretary for participation in the Direct Loan Program.

(b) * * *

(11) Comply with the provisions of paragraphs (d) through (i) of this section regarding student claims and disputes. *

(d) Borrower defense claims in an internal dispute process. The school will not compel any student to pursue a complaint based on a borrower defense claim through an internal dispute process before the student presents the complaint to an accrediting agency or government agency authorized to hear the complaint.

(e) Class action bans. (1) The school will not seek to rely in any way on a predispute arbitration agreement or on any other predispute agreement with a student who has obtained or benefited from a Direct Loan, with respect to any aspect of a class action that is related to a borrower defense claim, including to seek a stay or dismissal of particular claims or the entire action, unless and until the presiding court has ruled that the case may not proceed as a class action and, if that ruling may be subject to appellate review on an interlocutory basis, the time to seek such review has elapsed or the review has been resolved.

(2) Reliance on a predispute arbitration agreement, or on any other predispute agreement, with a student, with respect to any aspect of a class action includes, but is not limited to, any of the following:

(i) Seeking dismissal, deferral, or stay of any aspect of a class action.

(ii) Seeking to exclude a person or persons from a class in a class action.

(iii) Objecting to or seeking a protective order intended to avoid responding to discovery in a class action.

(iv) Filing a claim in arbitration against a student who has filed a claim on the same issue in a class action.

(v) Filing a claim in arbitration against a student who has filed a claim on the same issue in a class action after the trial court has denied a motion to certify the class but before an appellate court has ruled on an interlocutory appeal of that motion, if the time to seek such an appeal has not elapsed or the appeal has not been resolved.

(vi) Filing a claim in arbitration against a student who has filed a claim on the same issue in a class action after the trial court in that class action has granted a motion to dismiss the claim and, in doing so, the court noted that the consumer has leave to refile the claim on a class basis, if the time to refile the claim has not elapsed.

(3) Required provisions and notices:

(i) The school must include the following provision in any agreements with a student recipient of a Direct Loan for attendance at the school, or, with respect to a Parent PLUS Loan, a student for whom the PLUS loan was obtained, that include any agreement regarding predispute arbitration or any other predispute agreement addressing class actions and that are entered into after the effective date of this regulation: "We agree that neither we nor anyone else will use this agreement to stop you from being part of a class action lawsuit in court. You may file a class action lawsuit in court or vou may be a member of a class action lawsuit even if you do not file it. This provision applies only to class action claims concerning our acts or omissions regarding the making of the Direct Loan or the provision by us of educational services for which the Direct Loan was obtained. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Federal Direct Loan or the provision of educational services for which the loan was obtained."

(ii) When a predispute arbitration agreement or any other predispute agreement addressing class actions has been entered into before the effective date of this regulation and does not contain a provision described in paragraph (e)(3)(i) of this section, the school must either ensure the agreement is amended to contain the provision specified in paragraph (e)(3)(iii)(A) of this section or provide the student to whom the agreement applies with the written notice specified in paragraph (e)(3)(iii)(B) of this section.

(iii) The school must ensure the agreement described in paragraph (e)(3)(ii) of this section is amended to contain the provision specified in paragraph (e)(3)(iii)(A) of this section or must provide the notice specified in paragraph (e)(3)(iii)(B) of this section to

students no later than the exit counseling required under § 685.304(b), or the date on which the school files its initial response to a demand for arbitration or service of a complaint from a student who has not already been sent a notice or amendment.

(A) Agreement provision. "We agree that neither we nor anyone else who later becomes a party to this agreement will use it to stop you from being part of a class action lawsuit in court. You may file a class action lawsuit in court or you may be a member of a class action lawsuit in court even if you do not file it. This provision applies only to class action claims concerning our acts or omissions regarding the making of the Federal Direct Loan or the provision by us of educational services for which the Federal Direct Loan was obtained. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Federal Direct Loan or the provision of educational services for which the loan was obtained.'

(B) Notice provision. "We agree not to use any predispute agreement to stop you from being part of a class action lawsuit in court. You may file a class action lawsuit in court or you may be a member of a class action lawsuit even if you do not file it. This provision applies only to class action claims concerning our acts or omissions regarding the making of the Federal Direct Loan or the provision by us of educational services for which the Federal Direct Loan was obtained. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Federal Direct Loan or the provision of educational services for which the loan was obtained.'

- (f) Predispute arbitration agreements. (1)(i) The school will not enter into a predispute agreement to arbitrate a borrower defense claim, or rely in any way on a predispute arbitration agreement with respect to any aspect of a borrower defense claim.
- (ii) A student may enter into a voluntary post-dispute arbitration agreement with a school to arbitrate a borrower defense claim.
- (2) Reliance on a predispute arbitration agreement with a student with respect to any aspect of a borrower defense claim includes, but is not limited to, any of the following:
- (i) Seeking dismissal, deferral, or stay of any aspect of a judicial action filed by the student, including joinder with others in an action;
- (ii) Objecting to or seeking a protective order intended to avoid

responding to discovery in a judicial action filed by the student; and

- (iii) Filing a claim in arbitration against a student who has filed a suit on the same claim.
- (3) Required provisions and notices: (i) The school must include the following provision in any predispute arbitration agreements with a student recipient of a Direct Loan for attendance at the school, or, with respect to a Parent PLUS Loan, a student for whom the PLUS loan was obtained, that include any agreement regarding arbitration and that are entered into after the effective date of this regulation: "We agree that neither we nor anyone else will use this agreement to stop you from bringing a lawsuit concerning our acts or omissions regarding the making of the Federal Direct Loan or the provision by us of educational services for which the Federal Direct Loan was obtained. You may file a lawsuit for such a claim or you may be a member of a class action lawsuit for such a claim even if you do not file it. This provision does not apply to lawsuits concerning other claims. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Federal Direct Loan or the provision of educational services for which the loan
- (ii) When a predispute arbitration agreement has been entered into before the effective date of this regulation that did not contain the provision specified in paragraph (f)(3)(i) of this section, the school must either ensure the agreement is amended to contain the provision specified in paragraph (f)(3)(iii)(A) of this section or provide the student to whom the agreement applies with the written notice specified in paragraph (f)(3)(iii)(B) of this section.

was obtained."

- (iii) The school must ensure the agreement described in paragraph (f)(3)(ii) of this section is amended to contain the provision specified in paragraph (f)(3)(iii)(A) of this section or must provide the notice specified in paragraph (f)(3)(iii)(B) of this section to students no later than the exit counseling required under § 685.304(b), or the date on which the school files its initial response to a demand for arbitration or service of a complaint from a student who has not already been sent a notice or amendment.
- (A) Agreement provision. "We agree that neither we nor anyone else who later becomes a party to this predispute arbitration agreement will use it to stop you from bringing a lawsuit concerning our acts or omissions regarding the making of the Federal Direct Loan or the provision by us of educational services

- for which the Federal Direct Loan was obtained. You may file a lawsuit for such a claim or you may be a member of a class action lawsuit for such a claim even if you do not file it. This provision does not apply to other claims. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Federal Direct Loan or the provision of educational services for which the loan was obtained."
- (B) Notice provision. "We agree not to use any predispute arbitration agreement to stop you from bringing a lawsuit concerning our acts or omissions regarding the making of the Federal Direct Loan or the provision by us of educational services for which the Federal Direct Loan was obtained. You may file a lawsuit regarding such a claim or you may be a member of a class action lawsuit regarding such a claim even if you do not file it. This provision does not apply to any other claims. We agree that only the court is to decide whether a claim asserted in the lawsuit is a claim regarding the making of the Direct Loan or the provision of educational services for which the loan was obtained."
- (g) Submission of arbitral records. (1) A school must submit a copy of the following records to the Secretary, in the form and manner specified by the Secretary, in connection with any claim filed in arbitration by or against the school concerning a borrower defense claim:
- (i) The initial claim and any counterclaim.
- (ii) The arbitration agreement filed with the arbitrator or arbitration administrator.
- (iii) The judgment or award, if any, issued by the arbitrator or arbitration administrator.
- (iv) If an arbitrator or arbitration administrator refuses to administer or dismisses a claim due to the school's failure to pay required filing or administrative fees, any communication the school receives from the arbitrator or arbitration administrator related to such a refusal.
- (v) Any communication the school receives from an arbitrator or an arbitration administrator related to a determination that a predispute arbitration agreement regarding educational services provided by the school does not comply with the administrator's fairness principles, rules, or similar requirements, if such a determination occurs.
- (2) A school must submit any record required pursuant to paragraph (g)(1) of this section within 60 days of filing by the school of any such record with the

- arbitrator or arbitration administrator and within 60 days of receipt by the school of any such record filed or sent by someone other than the school, such as the arbitrator, the arbitration administrator, or the student.
- (h) Submission of judicial records. (1) A school must submit a copy of the following records to the Secretary, in the form and manner specified by the Secretary, in connection with any claim concerning a borrower defense claim filed in a lawsuit by the school against the student or by any party, including a government agency, against the school:
- (i) The complaint and any counterclaim.
- (ii) Any dispositive motion filed by a party to the suit; and
- (iii) The ruling on any dispositive motion and the judgment issued by the court.
- (2) A school must submit any record required pursuant to paragraph (h)(1) of this section within 30 days of filing or receipt, as applicable, of the complaint, answer, or dispositive motion, and within 30 days of receipt of any ruling on a dispositive motion or a final judgment.
- (i) *Definitions*. For the purposes of paragraphs (d) through (h) of this section, the term—
- (1) "Borrower defense claim" means a claim that is or could be asserted as a borrower defense as defined in § 685.222(a)(5), including a claim other than one based on § 685.222(c) or (d) that may be asserted under § 685.222(b) if reduced to judgment;
- (2) "Class action" means a lawsuit in which one or more parties seek class treatment pursuant to Federal Rule of Civil Procedure 23 or any State process analogous to Federal Rule of Civil Procedure 23;
- (3) "Dispositive motion" means a motion asking for a court order that entirely disposes of one or more claims in favor of the party who files the motion without need for further court proceedings;
- (4) "Predispute arbitration agreement" means any agreement, regardless of its form or structure, between a school or a party acting on behalf of a school and a student providing for arbitration of any future dispute between the parties.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2017-0100; FRL-9980-94-Region 5]

Air Plan Approval; Michigan; Revisions to Part 9 Miscellaneous Rules

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a request submitted by the Michigan Department of Environmental Quality (MDEQ) on February 2, 2017, and supplemented on November 8, 2017, to revise the Michigan state implementation plan (SIP) for carbon monoxide (CO). The revision incorporates changes to Michigan's Air Pollution Control Rules entitled "Emissions Limitations and Prohibitions-Miscellaneous." The revision updates existing source-specific rule requirements for ferrous cupola operations by removing obsolete rule language and makes a minor change to correct the citation to a Federal test method. The revision continues to result in attainment of the CO national ambient air quality standard.

DATES: This final rule is effective on August 20, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R05-OAR-2017-0100, All documents in the docket are listed on the www.regulations.gov website. Although listed in the index, 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 through www.regulations.gov or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Charles Hatten, Environmental Engineer, at (312) 886-6031 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT:

Charles Hatten, Environmental Engineer, Control Strategies Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, hatten.charles@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This supplementary information section is arranged as follows:

I. What are the State rule revisions? II. What action is EPA taking? III. Incorporation by Reference IV. Statutory and Executive Order Reviews

I. What are the State rule revisions?

On February 2, 2017, and supplemented on November 8, 2017, MDEQ submitted a request to incorporate revisions to Michigan's Air Pollution Control Rules in Chapter 336, Part 9—Emissions Limitations and Prohibitions—Miscellaneous (Part 9) in the Michigan SIP. Michigan submitted revisions to three separate rules in Part 9: R 336.1902—"Adoption of standards by reference" (Rule 902); R 336.1916— "Affirmative defense for excess emissions during start-up or shutdown" (Rule 916); and R 336.1930—"Emission of carbon monoxide from ferrous cupola operations" (Rule 930). This rule will only take action on Rule 930. The revisions to Rule 902 have already been approved into Michigan's SIP, and the revisions to Rule 916 will be addressed in a future action.

Michigan's Rule 930 specifies CO emission limits for large ferrous cupola operations with a melting capacity of 20 tons or more per hour. Rule 930 currently approved into the Michigan SIP only applies to ferrous cupola operations in Saginaw, Macomb, Oakland, and Wayne Counties in Michigan. The rule is designed to require installation of afterburner control system, or equivalent, which reduces the CO emissions from the ferrous cupola by 90 percent.

On May 3, 2018 (83 FR 19497), EPA published a notice of proposed rulemaking (NPR) proposing approval of Michigan's Part 9 Rule submitted by MDEQ on February 2, 2017, and supplemented on November 8, 2017, as a revision into Michigan's SIP. Specifically, we proposed to approve the revision that updates the applicability of Rule 930 to: (1) Remove an obsolete compliance date and requires immediate compliance, (2) remove the areas of the state that no longer contain ferrous cupola sources subject to the rule, and (3) correct the citation to a Federal test method to determine CO emission rates for rule compliance. The specific details of Michigan's SIP revision and the rationale for EPA's approval are discussed in the NPR.

EPA received no comments on the proposed action.

II. What action is EPA taking?

EPA is approving Michigan's Part 9, specifically for Rule 930 submitted by MDEQ on February 2, 2017, and supplemented on November 8, 2017, as a revision to the Michigan SIP.

III. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Michigan Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through www.regulations.gov, and at the EPA Region 5 Office (please contact the person identified in the FOR **FURTHER INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.1

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 Clean Air 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions

¹⁶² FR 27968 (May 22, 1997).

of the Paperwork Reduction Act (44 U.S.C. 3501 *et seg.*);

- 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 17, 2018. 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, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 9, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

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.

■ 2. In § 52.1170, the table in paragraph (c) is amended by revising the entry for "R 339.1930" under the heading "Part 9. Emission Limitations and Prohibitions—Miscellaneous" to read as follows:

§ 52.1170 Identification of plan.

(C) * * *

EPA-APPROVED MICHIGAN REGULATIONS

| Michigan citation | Tit | le | State effective date | EPA approval of | late | Comments |
|-------------------|---------------------------------------|-----------------------|----------------------|--|----------------|----------|
| * | * | * | * | * | * | * |
| | P | art 9. Emission Limit | tations and Prof | nibitions—Miscellaneous | | |
| * | * | * | * | * | * | * |
| ₹ 339.1930 | Emission of carbon rous cupola operat | | 12/20/2016 | 7/19/2018, [insert Federal tion]. | Register cita- | |
| * | * | * | * | * | * | * |

* * * * * * * [FR Doc. 2018–15339 Filed 7–18–18; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-8537]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the Federal Register on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at https:// www.fema.gov/national-floodinsurance-program-community-statusbook.

DATES: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 212–3966.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction

from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the Federal Register.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains. Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

| State and location | Community No. | Effective date authorization/cancellation of sale of flood insurance in community | Current effective map date | Date certain Federal assistance no longer available in SFHAs |
|--|------------------|--|----------------------------|---|
| Region I Massachusetts: Haverhill, City of, Essex County. Region V | 250085 | April 30, 1974, Emerg; February 16, 1983, Reg; July 19, 2018, Susp | July 19, 2018 | July 19, 2018. |
| Ohio: Fairfield County, Unincorporated Areas | 390158 | March 21, 1977, Emerg; April 17, 1989, | do * | Do. |
| Lancaster, City of, Fairfield County | 390161 | Reg; July 19, 2018, Susp July 28, 1975, Emerg; May 1, 1980, Reg; July 19, 2018, Susp | do | Do. |
| Pickerington, City of, Fairfield and Franklin Counties. Region VI | 390162 | June 11, 1976, Emerg; August 5, 1991, Reg; July 19, 2018, Susp | do | Do. |
| Oklahoma: | | | | |
| Billings, Town of, Noble County | 400347 | September 8, 1983, Emerg; June 19, 1985, Reg; July 19, 2018, Susp | do | Do. |
| Tribe of Ponca Indians of Oklahoma, Noble and Kay Counties. | 400239 | N/A, Emerg; July 15, 2008, Reg; July 19, 2018, Susp | do | Do. |
| Red Rock, Town of, Noble County | 400135 | June 12, 1975, Emerg; May 25, 1978, Reg; July 19, 2018, Susp | do | Do. |
| Region IX | | , | | |
| California: | | | | |
| Elk Grove, City of, Sacramento County | 060767 | N/A, Emerg; October 15, 2001, Reg; July 19, 2018, Susp | do | Do. |
| Folsom, City of, Sacramento County | 060263 | March 10, 1977, Emerg; January 6, 1982, Reg; July 19, 2018, Susp | do | Do. |
| Rancho Cordova, City of, Sacramento County. | 060772 | N/A, Emerg; September 15, 2004, Reg; July 19, 2018, Susp | do | Do. |
| Sacramento County, Unincorporated Areas. | 060262 | March 31, 1972, Emerg; March 15, 1979, Reg; July 19, 2018, Susp | do | Do. |

do = Ditto

Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: June 29, 2018.

Michael M. Grimm,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2018–15372 Filed 7–18–18; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 672

[Docket No. FTA-2015-0014] RIN 2132-AB25

Public Transportation Safety Certification Training Program

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Final rule.

SUMMARY: The Federal Transit Administration is issuing a final rule for the Public Transportation Safety Certification Training Program to provide revised minimum training requirements for Federal and State personnel and contractors who conduct safety audits and examinations of transit systems and for transit agency personnel and contractors who are directly responsible for safety oversight. The revised requirements reduce the number of training hours required by the interim training program.

DATES: The effective date of this rule is August 20, 2018.

FOR FURTHER INFORMATION CONTACT: For program issues, contact FTA, Office of Transit Safety and Oversight (telephone: 202–366–1783 or email: FTASafetyPromotion@dot.gov). For legal issues, contact Bruce Walker, FTA, Office of Chief Counsel (telephone: 202–366–9109 or email: Bruce.Walker@dot.gov). Office hours are Monday through Friday from 8 a.m. to 6 p.m. (EST), except Federal holidays.

SUPPLEMENTARY INFORMATION:

- I. Executive Summary
 - A. Statutory Authority
 - B. Summary of Major Provisions
 - C. Costs and Benefits
- II. Rulemaking Background
- III. Summary of NPRM Comments and FTA Responses
- IV. Revised Regulatory Evaluation
- V. Regulatory Analyses and Notices

I. Executive Summary

In the Moving Ahead for Progress in the 21st Century Act (MAP-21) (Pub. L. 112–141, July 6, 2012), Congress directed FTA to establish a comprehensive Public Transportation Safety Program (codified at 49 U.S.C. 5329), one element of which is the Public Transportation Safety Certification Training Program (PTSCTP). As a first step to implementing the PTSCTP, FTA developed requirements for the interim safety certification training program (interim training program) which became effective on May 28, 2015 (see 80 FR 10619). FTA then published a notice of proposed rulemaking (NPRM) in the **Federal Register** on December 3, 2015 (80 FR 75639), which generally proposed to adopt the interim training program requirements for the PTSCTP final rule. As noted in Appendix A, the requirements in this final rule reduce the number of required training hours from a total of 181 hours (22.625 days) to 143 hours (17.875 days).

More recently, Congress enacted the Fixing America's Surface Transportation Act ("FAST") (Pub. L. 114–94, Dec. 4, 2015). FAST did not make any amendments to 49 U.S.C. 5329(c)(1), the

statute authorizing the PTSCTP, that would affect today's rulemaking. Therefore, for convenience and accurate context, this rule will refer to MAP–21 throughout the preamble for consistency with the NPRM.

Today's rule revises the minimum training requirements for State Safety Oversight Agency (SSOA) personnel and contractors who conduct safety audits and examinations of public transportation systems that receive Federal transit funds. The rule also provides minimum training requirements for transit agency employees who are directly responsible for safety oversight of public transportation systems that receive Federal transit funds. Although not subject to this rule, pursuant to 49 U.S.C. 5329(c)(1), FTA personnel and contractors who conduct safety audits and examinations of rail public transportation systems will adhere to the applicable SSOA training requirements listed in Appendix A.

A. Statutory Authority

This rulemaking is issued under the authority of 49 U.S.C. 5329(c)(1), which requires the Secretary of Transportation to establish a public transportation safety certification training program for Federal and State employees, or other designated personnel, who conduct safety audits and examinations of public transportation systems, and employees of public transportation agencies directly responsible for safety oversight. The Secretary is authorized to issue regulations to carry out the general provisions of this statutory requirement pursuant to 49 U.S.C. 5329(c)(2) and (f)(7).

B. Summary of Major Provisions

Today's rule adds a new part 672, Public Transportation Safety Certification Training Program, to title 49 of the Code of Federal Regulations. The purpose of the rule is to provide minimum requirements to enhance the proficiency of transit safety oversight professionals. In general, FTA maintained much of what was proposed in the NPRM. The mandatory training requirements apply to personnel who conduct safety audits and examinations of rail transit systems, and transit personnel with direct safety oversight responsibility of rail transit systems. Participation in the PTSCTP remains voluntary for State personnel, employees of bus transit agencies and the contractors directly responsible for safety oversight of public bus transportation systems.

C. Costs and Benefits

In general, FTA has retained the approach to costs contained in the NPRM. FTA quantified, to the extent possible, the costs associated with this rule. FTA expects that the codification of the PTSCTP will help promote a safety culture within the transit industry. This safety culture should help instill a transit agency-wide appreciation for shared goals, shared beliefs, best practices, and positive and vigilant attitudes towards safety.

Where appropriate, FTA has modified the analysis for this rule from that of the NPRM. For example, in response to comments, FTA revised the hourly wage rate upward to better reflect average labor rates including benefits within the public transportation sector and factored in modest travel costs for attendance. Also, FTA has eliminated the 36-hour Transit System Security course and the 2-hour SMS Gap online course as mandatory components of the PTSCTP program. This change has resulted in a reduced burden on course participants. The regulatory analysis is conducted in two parts. First, under Executive Order 12866, by comparing the costs of issuing the rule in relation to practice prior to MAP-21 and second, under Executive Order 13771, since this final rule is considered a deregulatory action due to the reduction in existing safety training requirements.

FTA used data from the Transportation Safety Institute (TSI) and reviewed the public transit workforce's participation in FTA's voluntary safety training programs to establish a maximum and minimum number of personnel, including contractors, that would be affected by the PTSCTP. The interim training program on which this rule is modeled became effective on May 28, 2015. Thus far, enrollment in the interim training program aligns with the assumptions FTA posed in the NPRM.

To determine annual costs for recipients to implement PTSCTP requirements, we continue with a minimum and maximum case scenario. For the minimum case, we maintain an assumption that all designated personnel under this program have received the Transit Safety and Security Program (TSSP) Certificate and require only the safety management system (SMS) portion of the coursework described in Appendix A of this rule. For the maximum case, we assume no one subject to the rule has a TSSP Certificate. In this scenario, all designated personnel will have to complete both the TSSP (minus the Transit System Security (TSS) course)

and SMS coursework over a three (3) vear period. However, in response to comments, some travel costs are now included for attending courses if participants are unable to attend locally. Also, since TSSP training was previously provided by TSI, the cost of that cannot be attributed to this final rule. The cost numbers were adjusted accordingly. As a result of the changes above, and extending the analysis period to ten years instead of three to include refresher training and staff turnover, the maximum cost estimate is adjusted to approximately \$1.0 million annualized at 7 percent discount rate instead of the undiscounted \$2.6 million per year over a three year period as noted in the NPRM.

This final rule will replace the interim safety training program provisions issued in February 2015. The final rule eliminates two training provisions as mentioned above. The cost of the final rule therefore reduces the costs of the interim provisions by over \$51,000 over a ten year period, discounted at a 7 percent rate for the minimum case scenario and \$1.6 million respectively for the maximum case scenario, resulting in a net benefit for the agencies. This results in an annualized cost savings (benefits) of \$7,300 and \$2,258 respectively for the two scenarios at the 7 percent discount rate.

We note that these costs do not reflect costs associated with any additional countermeasures that better trained personnel will take to increase safety that they would not have identified prior to the training. Pursuant to 49 U.S.C. 5329(e)(6)(C)(iv), recipients may use up to 0.5 percent of their FTA formula funds to cover up to 80 percent of costs of PTSCTP eligible expenditures.

II. Rulemaking Background

On October 3, 2013, FTA issued an Advance Notice of Proposed Rulemaking (ANPRM) in the Federal **Register** on all aspects of FTA's safety authority, including the training program. (See 78 FR 61251 at http:// www.gpo.gov/fdsys/pkg/FR-2013-10-03/ pdf/2013-23921.pdf). FTA noted that there are discrete and different skill-sets required for those who perform safety audit and examination functions compared to those who are directly responsible for safety oversight. Recognizing this distinction, FTA outlined its vision for the PTSCTP which included a wholly new FTAsponsored training curriculum to enhance the technical proficiency of each category of these safety professionals.

On April 30, 2014, FTA published a document in the **Federal Register** requesting comment on its proposed vision for the interim training program. A number of the proposed requirements for the interim training program were based partly on recommendations provided by commenters to the ANPRM (see 79 FR 24363). FTA evaluated comments received in response to the document and promulgated the final interim training program requirements in a **Federal Register** document dated February 27, 2015 (see 80 FR 10619).

On December 3, 2015, FTA published a Federal Register document proposing to adopt the interim training program as the requirements for the PTSCTP (see 80 FR 75639). FTA reviewed comments to the NPRM and with this document promulgates the PTSCTP rule as 49 CFR part 672. This rule primarily applies to recipients of Chapter 53 funding; however, pursuant to 49 U.S.C. 5329(c)(1), the SSOA training requirements listed in Appendix A also apply to FTA personnel and contractors that conduct safety audits and examinations of rail transit systems.

III. Summary of NPRM Comments and FTA Responses

FTA proposed to utilize the interim training program requirements as the foundation for the PTSCTP. Similar to the interim training program, FTA proposed that the initial focus of the PTSCTP should be on enhancing the technical proficiency of safety oversight professionals in the rail transit industry. However, recognizing that safety is a priority for all public transit providers, safety oversight personnel of other modes of public transportation were encouraged to participate voluntarily. For that reason, FTA proposed that the initial mandatory PTSCTP requirements provide safety management system and technical training for Federal and SSOA personnel and their contractors, and rail transit agency personnel directly responsible for safety oversight of rail transit systems. Safety oversight personnel of recipients such as State Departments of Transportation (DOTs) and bus transit providers would be voluntary participants.

Nineteen commenters responded to the NPRM as follows: Seven (7) public transportation agencies; three (3) State Safety Oversight Agencies; one (1) member of the public; one (1) Federal safety agency; two (2) national safety associations; two (2) national public transportation associations; two (2) State Department of Transportations (DOTs); and, one (1) letter representing five (5) State DOTs. FTA reviewed all comments and noted that only one commenter provided remarks that were not responsive to the scope of the NPRM. Following is a summary of the comments received and FTA's responses.

Section 672.1 Purpose

FTA proposed to implement 49 U.S.C. 5329(c)(1), by establishing a uniform curriculum of safety certification training to enhance the technical proficiency of individuals who are directly responsible for safety oversight of public transportation systems not subject to the safety oversight requirements of another Federal agency. FTA also noted that the rule would not preempt a State from implementing its own safety certification training requirements for public transportation systems subject to its jurisdiction.

A commenter to this section expressed appreciation for FTA's effort to adopt a uniform training curriculum and establish guidelines for all individuals who are directly responsible for safety oversight of public transportation agencies. Another commenter noted that FTA's framework provides a training standard for system safety and ensures a basic level of competency in SMS across the public transportation industry.

FTA Response: Upon review, FTA determined the proposed text requires clarification and is revising the text of paragraph (a) to include reference to personnel who conduct safety audits and examinations of public transportation agencies in this section. Additionally, the phrase "not subject to the safety oversight requirements of another Federal agency" that was proposed in the NPRM is not included in the final rule because the definition for "public transportation agency" indicates this exception. The remainder of the proposed text is included in the final rule.

Section 672.3 Scope and Applicability

FTA proposed that in general, the rule would apply to all recipients of Federal public transportation funding under Chapter 53 of Title 49 of the United States Code. FTA noted, however, in order to manage Federal and local resources, the initial mandatory requirements would apply to SSOA personnel and contractors conducting safety audits and examinations, as well as Rail Transit Agency (RTA) personnel directly responsible for safety oversight of rail transit systems not subject to the requirements of the Federal Railroad Administration. All other recipients of Chapter 53 funding would be able to participate voluntarily in the PTSCTP.

In response to the NPRM, one commenter disagreed with FTA's approach and recommended that both rail and bus transit system personnel be required participants in the PTSCTP. The commenter noted that motor vehicle crashes are the second-leading cause of unintentional death in the United States. The commenter stated that bus operations would benefit from defensive driving training as well as SMS and other specific safety training.

Conversely, commenters affiliated with State DOTs and small bus transit providers agreed that FTA should not require safety oversight personnel from these entities to be mandatory participants. Many of these commenters referred to the excellent safety record of bus transit providers to support the exclusion of these entities from mandatory PTSCTP participation. The commenters stated that FTA should limit regulatory burdens on States and subrecipient transit agencies that receive funding for rural transit. Several commenters indicated that the final rule should expressly affirm that it does not apply to bus service providers other than on a voluntary basis.

A few commenters indicated that the rule should be revised to include FTA personnel and its contractors that conduct safety audits and examinations as mandatory participants. These commenters noted that FTA should be subject to the same training requirements as SSOA employees and contractors.

FTA Response: FTA continues to believe the initial focus of the PTSCTP should be on rail public transit providers and the Federal and State personnel who conduct safety audits and examinations. As noted in the preamble of the ANPRM published in 2013, the intent is to initially focus regulatory efforts on those responsible for safety oversight of rail transit systems. FTA adopted this approach because the increased potential for catastrophic accidents, loss of life, and property damage associated with rail transit warranted the most immediate attention (see 78 FR 61252).

FTA reiterates that although the initial regulatory focus is primarily on rail safety, safety in the bus transit industry will not be ignored. In addition, FTA continues to expand resources and partner with groups that promote bus safety. Recognizing that resources must be expended judiciously and enforcement efforts must be prioritized, FTA believes the current safety environment within the bus transit industry supports the option for voluntary participation in FTA's safety training program.

However, it is important to note that FTA is developing a more systematic safety reporting regime for the public transit industry. FTA is also increasing its capability for reviewing and analyzing safety data and trends across the industry. Should analysis of safety data and trends indicate increased safety risk in the bus transit industry, FTA retains authority to implement mandatory training requirements for bus transit safety oversight personnel.

In response to commenters who indicated this rule should apply also to FTA personnel conducting safety audits and examinations, FTA notes this rulemaking applies specifically to recipients of Federal transit funds under Chapter 53, Title 49 of the United States Code. However, FTA agrees that FTA personnel and contractors should observe the same training requirements as SSOA personnel and contractors. Accordingly, pursuant to 49 U.S.C. 5329(c)(1), this final rule requires FTA safety oversight personnel and contractors that conduct safety audits and examinations of rail fixed guideway public transportation systems to adhere to the same SSOA training courses noted in Appendix A. For the reasons herein, the text proposed in the NPRM is included in the final rule with clarifying edits. In paragraph (b), the phrase "that are not subject to the requirements of the Federal Railroad Administration (FRA)" was removed because the definition of "rail fixed guideway public transportation systems" includes the statement that such systems are not subject to FRA's jurisdiction. The text of paragraphs (a) and (c) are included in the final rule as proposed in the NPRM.

Section 672.5 Definitions

This section proposed definitions for some key terms in the rule. Many of the terms carry the same or similar meaning as used in other FTA documents. Additionally, some new terms were proposed with definitions consistent with common use.

Seven commenters responded to this section. One commenter stated that the term "contractor" should be revised to include RTA contractors that implement the RTA's safety program. Another commenter indicated the definition should be broadened to include all those who provide contracted services, supplies, or equipment to FTA recipients. Yet another commenter indicated the definition should be revised to include individuals and entities that perform safety-related tasks for an RTA through contract or other agreement.

Two commenters indicated the terms "safety audit" and "safety examination" required clarification. One questioned whether there is a practical difference between an examination conducted as part of the audit and the analysis of acts performed in conjunction with the examination. The other commenter indicated the definition for both terms require more specificity in order to distinguish between the activities associated with the terms and clarify who performs an examination.

A commenter indicated that the definition for "designated personnel" should be revised to include FTA safety oversight personnel and contractors in order to make them subject to this rule. Other commenters indicated that FTA needed to provide more clarity regarding the definition for "directly responsible for safety oversight" relative to RTA designated personnel. Another commenter suggested that the definition for "State Safety Oversight Agency" should not include reference to 49 CFR part 659 since that rule is set to expire.

FTA Response: FTA believes the definition for "contractor" proposed in the NPRM sufficiently describes entities that provide safety audit and examination services to FTA and SSOAs. However, FTA agrees with commenters who indicated the definition should be amended to include contractors that provide services to public transportation agencies. FTA also amended section 672.13 to include RTA contractors.

With regard to commenters who recommended revising the definition for "designated personnel" to include FTA personnel and contractor support, as noted earlier, this rule generally applies to FTA recipients; therefore, FTA personnel and contractors are not included in this definition. However, as noted with the "contractor" definition, subparagraph (1) of this definition is revised to also include contractors that provide safety oversight services to rail transit agencies.

FTA concurs with commenters regarding the definition for "directly responsible for safety oversight." For clarity, FTA is revising the definition of the term relative to section 672.13(a), in recognition that RTA safety oversight personnel are already quite familiar with the safety oversight program requirements pursuant to 49 CFR part 659.

With regard to the terms "safety audit" and "safety examination", FTA agrees with those commenters who indicated the proposed definition for both terms should be reconciled. The terms are not unknown nor uncommon to those responsible for safety oversight

of RTA systems. FTA, SSOA, and RTA personnel are familiar with activities associated with safety audits and examinations as the terms relate to 49 CFR part 659 requirements, as well as the new SSO program rule at 49 CFR part 674. Further, it is unreasonable to interpret the term "examination" as it appears 49 U.S.C. 5329(c)(1) to refer to anything other than examinations related to the safety of public transportation systems. Therefore, to remain consistent with the terms as they appear in statute, the term safety audit will be included in the final rule but the term "safety examination" will be modified to "examination" to align with the definition as it appears in 49 CFR 670.5. It is also noted that safety audits and examinations will generally be conducted by Federal and/or State personnel and contractors.

Lastly, FTA agrees in part with the commenter who suggested the definition of "State Safety Oversight Agency' should be revised in reference to 49 CFR part 659. FTA notes 49 U.S.C. 5329(d)(2) provides an RTA's System Safety Program Plan (SSPP) developed pursuant to 49 CFR part 659 shall remain in effect until FTA publishes a final rule for Public Transportation Agency Safety Plans. SSOAs will continue to oversee RTAs' SSPPs until the RTAs are required to adopt Public Transportation Agency Safety Plans in compliance with the future final rulemaking under 49 U.S.C. 5329(d). In recognition of this fact, this definition is revised in the final rule to include reference to the new rule at 49 CFR part 674, as well as 49 CFR part 659. The remaining definitions proposed in the NPRM are included in this rule with minor edits to certain terms to ensure consistency with other FTA safety rulemakings.

Section 672.11 Designated Personnel Who Conduct Safety Audits and Examinations

FTA proposed that the SSOA identify personnel who conduct safety audits and examinations of the RTA(s) subject to its jurisdiction. In general, those identified would be SSOA employees and contractors whose duties include on-site safety audits and examinations of rail public transportation systems. FTA proposed this would include the SSOA managers and supervisors with direct authority over such SSOA personnel.

FTA proposed that once identified, designated personnel would have 3 years to complete the applicable PTSCTP training requirements. FTA also proposed that designated personnel would be required to complete at least

one hour of refresher training every 2 years after completing the initial mandatory training. FTA further proposed that the SSOA would have discretion to determine the subject area and duration for such training. FTA also proposed that the interim training program requirements become the initial training requirements for this rule. The interim requirements were republished as Section IV of the NPRM. However, FTA did not seek comment on the curriculum of the interim training program since it was developed through public notice and comment and effective only since May 28, 2015.

Five commenters responded to this section. One commenter indicated that State personnel, such as commissioners and directors, should not be required to participate in the PTSCTP requirements. The commenter stated that these individuals do not actually conduct safety audits and examinations of the rail transit systems under their jurisdiction. Other commenters indicated that FTA personnel and contractors should be included as designated personnel.

Regarding refresher training, several commenters felt the two-year interval for refresher training was sufficient. However, one commenter disagreed with the two-year timeframe, indicating that more robust refresher training should be required annually with a minimum requirement of at least four hours of training. The commenter also stated that the initial timeframe for completing PTSCTP requirements should be less than the three years FTA proposed. One commenter recommended that FTA be more specific as to the required elements for refresher training. Another commenter stated that FTA should require at least one class of refresher training every two years without identifying a time limit for the class. Yet another commenter stated that refresher training should at minimum include the "technical training component" and "knowledge of agency" elements outlined in Section IV of the NPRM.

FTA Response: In general, FTA believes those with direct management and supervisory responsibility of SSOA personnel and contractors that conduct safety audits and examinations should be subject to the PTSCTP training requirements. However, as indicated by a commenter, there are SSOA management personnel who do not directly oversee SSOA personnel and contractors. Conversely, there are managers and supervisors who do. In either case, FTA recognizes an SSOA is better situated to determine which managers and supervisors require

technical knowledge or perform functions identified in the technical training plan each SSOA is required to develop to comport with 49 U.S.C. 5329(e)(3)(E). For example, knowledge of railroad components is required only by those individuals actually conducting the examinations and audits of those specific railroad components, but not necessarily knowledge required of SSOA managers.

In short, some SSOA managers and supervisors will not be subject to PTSCTP requirements; however, those with direct supervisory responsibility of SSOA personnel and contractors subject to this part should share a common framework for understanding issues of risk and mitigation. For that reason, these managers and supervisors should at minimum undertake the SMS and TSSP curriculum identified in Appendix A. As indicated earlier, the SŠÕA will consult with FTA as it develops its technical training plan. This consultation should assist the SSOA with determining which of its personnel and contractor support should participate in the PTSCTP. However, FTA does not expect directors or commissioners, or similar State DOT personnel not involved in the day-today operations of an SSOA to be identified as designated personnel.

In response to comments suggesting the proposed three-year timeframe for completing the initial PTSCTP requirements is too long, FTA notes that RTAs and SSOAs already engage in significant safety training including the voluntary TSSP which underpins the PTSCTP requirements. FTA disagrees that the PTSCTP requirements should be completed in less than three years. FTA believes such a requirement would unduly burden recipients while not significantly contributing to public transportation safety. Furthermore, FTA notes that 49 U.S.C. 5329 provides additional tools that FTA can utilize if it finds that targeted training or remedial action is required immediately.

In response to comments regarding proposed refresher training requirements, from the onset FTA has stated its intent to take a comprehensive approach to safety training requirements. FTA recognizes there will be safety training requirements in other rules FTA is implementing for the National Public Transportation Safety Program (National Safety Program) which may apply also to some PTSCTP participants. FTA continues to believe that refresher training should be relevant to a recipient's specific circumstances and the recipient is in the best position to determine the subject

matter and timeframe allotted for such training. In addition, FTA will provide guidance to assist recipients with identifying relevant subject matter for safety oversight refresher training.

FTA believes the proposed requirements are sufficient and that a one-year training completion requirement or annual refresher training requirement would not provide significant value considering other safety training initiatives will be occurring during the same timeframe. For these reasons, the proposed rule text is included in the final rule except FTA omitted paragraph (c), which provided that the Reference Document was available on the FTA website. The training curriculum and requirements are now found in Appendix A to this

Section 672.13 Designated Personnel of Public Transportation Agencies

In the NPRM, FTA proposed that a recipient be required to identify its personnel whose job function is "directly responsible for safety oversight" of the public transportation system. FTA noted that the unique organizational framework of public transit systems does not reasonably allow for uniform designation of positions or functions that are "directly responsible for safety oversight."

FTA stated that once identified, designated personnel would have three years to complete the applicable training for the PTSCTP. FTA also proposed that designated personnel would be required to complete at least one hour of refresher training every two years following the completion of the initial PTSCTP requirements. FTA further stated that RTA personnel would be mandatory participants while State DOT and bus transit system personnel would be voluntary participants. All recipients would have discretion to determine the subject area and time for biannual refresher training. Seven commenters provided responses to this section. In general, commenters responded to FTA's proposed timeframe for completing the PTSCTP requirements; however, two commenters indicated they were unable to locate the specific requirements of the Reference Document.

One commenter stated that employees of rail systems should be required to meet the training requirements as soon as possible in order to ensure the safest transit operations for passengers. Several other commenters indicated that the three-year period for completing the required training should be extended because of potential scheduling conflicts. The commenters noted that

FTA's course availability is not always conducive to transit personnel being able to attend the training. Some commenters also indicated that there may be instances where the course location could interfere with attendance. One commenter suggested that FTA provide its training schedule as far in advance as possible in order to assist recipients with minimizing travel costs. The commenter also recommended that FTA increase the number of online courses.

One commenter indicated that FTA should not require the Transit System Security (TSS) course as a mandatory component of the PTSCTP curriculum since security matters are not generally under the purview of safety oversight personnel. Two commenters noted that the proposed rule required rail transit agencies to provide technical training to SSOA personnel and suggested that FTA instead develop specific rail transit technical training courses.

Regarding the requirement to identify personnel who are directly responsible for safety oversight, one commenter recommended that such personnel be limited to policymaking officials with broad safety accountabilities, rather than each employee who has a function or duty specific to an agency's safety plan. The commenter suggested that the rule apply only to those individuals who are accountable for the overall development, implementation, and review of the agency's safety program. Another commenter indicated that FTA use an approach in which it amplifies an SMS model where implementation of the agency safety plan is the shared responsibility of every position within the system (i.e., safety, operations, maintenance, human resources, training, and administration). The commenter further suggested that FTA provide guidance, or identify criteria to assist agencies with objectively identifying staff subject to the PTSCTP requirements.

FTA Response: As noted in response to the section above, FTA disagrees with commenters who suggested that three years is not enough time to complete the required training. FTA has no indication that the current level of course offerings will not support completion of the requirements within three years. Review of the registration data website for interim training program registration indicates a significant number of those enrolling in the PTSCTP have already completed all, or some portion of the required TSSP component of the certificate program. However, FTA is providing additional course delivery dates to alleviate the potential burden due to the perceived lack of availability.

To facilitate course availability and predictability, FTA will continue to expand its capacity for delivering the PTSCTP curriculum at sites around the country and publish schedules as early as possible. Where appropriate, FTA will also work on expanding web based courses to increase training opportunities and further reduce costs associated with the PTSCTP.

Regarding SSOA training by RTAs, FTA did not propose a requirement for RTAs to provide technical training to SSOA personnel. However, FTA encourages SSOAs and RTAs to engage in joint training as much as practicable. This collaboration will only serve to promote a common framework of knowledge and improve communication between the RTA and the State regulator. Any training agreements between SSOAs and RTAs will be developed between the respective parties. If an RTA incurs additional expenses when including SSOA personnel with its training, then the parties can negotiate reimbursement for such expenses since SSOA training is an eligible expenditure of 49 U.S.C. 5329(e) grant funds.

FTA disagrees with commenters who suggested that FTA identify designated personnel for public transportation agencies. As commenters indicated in response to question 52 of the ANPRM that preceded the NPRM to this rule, each agency has its specific organizational construct and assignment of safety oversight functions. FTA continues to believe that each agency should have discretion to determine which functions and positions are directly responsible for safety oversight of the agency. However, FTA will provide guidance to assist RTAs with objectively identifying such personnel.

FTA agrees with commenters who indicated that employees who are in a position to be accountable for the development, implementation, and review of the agency's safety program should participate in the PTSCTP. This would also include RTA contractors. But the designation should not be limited only to personnel with management responsibility for the agency's safety plan. The designation should also include staff with primary responsibility for developing, implementing, and monitoring the agency's safety plan, as well as personnel who implement and execute SSOA requirements at the RTA. Depending on the size and organizational framework of the agency, this could be a few personnel or a sizable office or branch. The following guidance is provided to assist RTAs with identifying designated personnel:

SSOA's Program Standard—Processes and procedures an RTA must have in place to comply with the standard: Who at the RTA is responsible for developing, implementing or maintaining the following elements of the program standard?

(1) Program management;

(2) Program standard development;(3) Program policy and objectives;

(4) Oversight of the agency safety plans and internal safety reviews (who will respond to the SSOA if the SSOA determines the plans are inadequate?); (5) Triennial SSOA audits of Rail

(5) Triennial SSOA audits of Rail Public Transportation Agency Safety Plans (who will participate in the audit process and follow up on any findings or recommendations?);

(6) Accident notification (who is responsible for making appropriate notifications to FTA, SSOAs or when

applicable FRA?);

(7) Investigations (who will conduct internal accident investigations or coordinate RTA investigations in accordance with the SSO program standard and any agreements in effect?), (if the RTA does not agree with elements of an SSOA report, who will submit a written dissent from the report?);

(8) Corrective action plans (CAPs) (who is responsible for developing and carrying out the CAPs required by the SSOA?), (who will manage an issued CAP, identifying steps to minimize, control, correct, or eliminate the risks and hazards identified by the CAP, the schedule for taking those actions, and the individuals responsible for taking those actions?), (who will periodically report to the SSOA on its progress in carrying out the CAP?), (who will collect, track, and analyze data on occurrences to develop leading indicators, to prevent the likelihood of future events, and to inform the practice of SMS across the RTA?).

FTA recognizes recipients may have questions as to which positions or functions should be designated as PTSCTP participants. Recipients may contact FTA via email at FTASafetyPromotion@dot.gov for assistance.

For the reasons herein, proposed paragraph (a) is revised to include RTA contractors and the phrase "not subject to the safety oversight of another Federal agency" is removed because the definition of "rail fixed guideway public transportation systems" includes the statement that such systems are not subject to FRA's jurisdiction. Paragraphs (b) and (c) are included in the final rule as proposed in the NPRM and proposed paragraph (d) is omitted now that the PTSCTP curriculum and training

requirements are listed in Appendix A to this rule.

Section 627.15 Evaluation of Prior Certification and Training

In the NPRM, FTA acknowledged that participants who have completed safety training from entities other than FTA should be able to have that training reviewed to determine if it is equivalent to the competencies of the PTSCTP curriculum. To that end, FTA proposed that a participant provide official documentation to FTA from the organization that conducted the training. FTA stated that the documentation should indicate the date(s) and subject matter of the training. In addition, the participant would be required to provide a narrative summary of the training objectives and the competencies obtained as a result of the training.

Six commenters responded to this section. In general, commenters agreed that FTA should review other safety training for PTSCTP equivalency. However, most did not agree with FTA's proposed process. Three commenters indicated that FTA should proactively evaluate training provided by other organizations. Commenters indicated the participant should not have to describe how the training meets the competency of the PTSCTP curriculum. One commenter recommended that FTA "grandfather" existing transit agency personnel who possess five years of experience executing the requirements of 49 CFR part 659. The commenter also stated that FTA should provide PTSCTP credit for personnel who possess a Certified Safety Professional credential/ license. Another commenter suggested that FTA broadly and favorably consider equivalent training requests from those holding safety credentials, and degrees in safety. Lastly, one commenter noted that FTA should establish an objective measure for evaluating prior training and certification that is predictable, transparent, and fast.

FTA Response: In general, FTA agrees with commenters who indicated there should be an expedited and transparent process for evaluating safety training provided by entities other than FTA. To that end, FTA continues to refine its process for evaluating a participant's prior safety training. At this time, FTA is not prepared to provide independent approval of prior safety training or safety professional certifications without the participant providing official documentation and describing how the training or designation meets the objectives of the specific requirements of the PTSCTP. As the training program matures, FTA

anticipates that it will offer a list of courses and training that meet the PTSCTP requirements. Accordingly, the final rule includes the text as proposed in the NPRM.

Section 672.21 Records

In the NPRM, FTA noted that an essential requirement of any training program is the maintenance of adequate records of training. To that end, FTA proposed to maintain an electronic record of each PTSCTP participant via its online enrollment process. However, FTA stated that the recipient would be required to ensure that its personnel periodically update their information with his or her course completion information. Designated personnel can enroll for the program and update their individual training records as they complete the applicable training requirements by following the instructions provided at FTA's training website. The following web address provides participants with enrollment and registration information: https:// www.transit.dot.gov/regulations-andguidance/safety/safety-training. Further, each recipient will be responsible for maintaining an updated training record for its designated personnel.

Additionally, FTA proposed that each SSOA maintain training records to document the technical training of its designated personnel for at least five years from the date the record is created. FTA noted this documentation would assist the SSOA in complying with the grant requirements in accordance 49 U.S.C. 5329(e)(3)(E) by documenting that SSOA personnel and contractors have received training to perform requisite safety oversight functions.

FTA received three comments to this section. One commenter indicated this section should be revised to require FTA to also maintain records of its personnel and contractors that are subject to PTSCTP training requirements. Commenters agreed that designated personnel should enroll through FTA's safety database; however, two commenters indicated that FTA should be responsible for updating the participant's training completion information, not the recipient.

One commenter stated that an SSOA should not be responsible for maintaining training records for its contractors. The commenter stated that SSOAs should be able to require a contractor to provide certification showing the contractor has completed the required training. The commenter suggested that once a contractor has provided the initial documentation, the SSOA should not be required to maintain their training records and the

contractor should be responsible for maintaining their own records. The commenter also indicated that SSOA management should be able to rely on the FTA database to track the progress and status of SSOA personnel and contractors without the need for additional tracking mechanisms.

FTA Response: FTA concurs with commenters who indicated that FTA should administer and maintain the records for PTSCTP participants. However, FTA's ability to access participant training records for the PTSCTP does not relieve a recipient of the responsibility for ensuring its designated personnel, including its contractors, are in compliance with this part. The recipient is in the best position to ensure its designated personnel are timely updating course completion information. Furthermore, this process will assist the recipient with certifying compliance with this part.

FTA also agrees that a recipient, including an SSOA, should not be responsible for developing and maintaining training records for contractors. The contractor should be responsible for documenting and maintaining training records for its personnel. However, the recipient is responsible for ensuring its contractors comply with this part. To that end, a recipient may require its contractors to provide timely training documentation for contractor personnel subject to this part. To assist with grant documentation requirements, an SSOA should retain records of both its personnel and contractors in accordance with the timeframe prescribed in section 672.21(c) of this part.

As noted previously, this rule does not apply to FTA personnel and contractors. However, training records for FTA personnel are maintained in accordance with Federal standards; therefore, FTA disagrees with commenters who indicated this section should be revised to apply to FTA. However, as indicated by commenters, paragraph (b) is amended by replacing the term "maintain" with the term "retain" in reference to an SSOA's responsibility for the training records of its contractors. Paragraph (a) is included in the final rule as proposed, but subparagraphs (c)(1) through (5) are not included because Appendix A provides information required for SSOA technical training records.

Section 672.23 Availability of Records

FTA proposed a requirement for the safekeeping and limited release of information maintained in accordance with the requirements of this part. FTA stated that information maintained in the training records should not be released without the consent of the participant for whom the record is maintained, except in limited circumstances. FTA further noted that a participant should receive a copy of his or her training records without cost to him or her upon request.

In the NPRM, FTA stated that a recipient would be required to provide appropriate Federal and SSOA personnel access to all of the recipient's facilities where required training is conducted. In addition, the recipient would be required to grant access to all training records required to be maintained by this part to appropriate U.S. Department of Transportation personnel and appropriate State officials who are responsible for safety oversight of public transportation systems. Additionally, a recipient would provide information regarding a participant's training when requested by the National Transportation Safety Board when such request is made as part of an accident investigation.

FTA Response: FTA received no comments directly related to this section. Accordingly, the text proposed in the NPRM is included in the final rule.

Section 672.31 Requirement To Certify Compliance

FTA noted in the NPRM that recipients are required annually to certify their compliance with Federal grant requirements as a condition for receiving Federal funding. FTA proposed that recipients for whom the PTSCTP training requirements are mandatory should self-certify compliance with this part through the annual FTA certification and assurances process. FTA proposed that the recipient identify someone within the organization as authorized to certify compliance with this part on behalf of the recipient.

One commenter to this section stated that FTA should annually certify its compliance with the PTSCTP requirements. Two other commenters indicated that similar to FTA's current annual certification and assurance process, a recipient's chief executive, such as the General Manager or equivalent, should be the official authorized to certify compliance. One of the commenters stated that a recipient's board of directors primarily performs policy-setting duties and should not be asked to certify safety compliance as it would be beyond their scope. Lastly, one commenter asked if the annual certification requirement also applied to SSOAs.

FTA Response: The proposed rule stated that the recipient's governing body or authority should identify the person responsible for certifying the recipient's compliance with this part. FTA did not indicate that the governing body or chief executive would specifically have to certify the recipient's compliance with this part.

Currently, recipients undergo FTA's annual self-certification and assurance process as a condition of receiving Federal transit funds administered through FTA (see https:// www.fta.dot.gov/funding/granteeresources/certifications-and-assurances/ certifications-assurances). Each recipient, including an SSOA, is required to annually certify compliance with numerous Federal requirements as a condition for receiving Chapter 53 funds. However, FTA is not a recipient; therefore, FTA is not included in the annual certification process. For recipients however, annual certification of compliance with this part will now be included with FTA's annual certifications and assurance. Consequently, a recipient is required to designate an authorized representative for the purpose of signing the certification on behalf of the recipient. Accordingly, the text proposed in the NPRM is included in the final rule.

Section 672.33 Compliance as a Condition of Financial Assistance

This section was proposed in the NPRM to outline options available to FTA when a recipient does not comply with the requirements of this part. This section indicated the Administrator's discretion to withhold Federal funds and provided a notice and comment period for recipients.

Two commenters responded to this section. One commenter suggested the section be revised to include its applicability to SSOAs unless they are considered recipients. The other commenter indicated that absent clarification regarding how to identify designated personnel there is the possibility for an uneven identification of personnel across different agencies which could lead to a situation, where in hindsight, the Administrator may decide that a recipient has failed to comply with the requirements.

FTA Response: FTA has reviewed this section in conjunction with the provisions of the Public Transportation Safety Program Safety Program (see 49 CFR part 670). FTA has determined that the provisions therein provide a recipient with sufficient notice and due process regarding the Administrator's authority and enforcement actions for noncompliance with this part.

Therefore, FTA is not including proposed section 672.33 in this final rule.

Appendix A: Public Transportation Safety Certification Training Program

FTA proposed adopting the interim training program requirements listed in Section IV of the NPRM as the initial training requirements for the PTSCTP. FTA noted that the interim requirements were developed with public notice and comment and only became effective on May 28, 2015. For that reason, FTA only requested comments about the effectiveness of the curriculum and technical training requirements.

A number of commenters addressed FTA's proposed implementation of the PTSCTP and its applicability which we have already discussed; however, one commenter directly addressed the effectiveness of the proposed curriculum. The commenter noted that FTA should not require the Transit System Security (TSS) course as a mandatory component of the PTSCTP curriculum since security matters are not generally under the purview of safety oversight personnel.

FTA Response: FTA agrees with the commenter and has revised the PTSCTP curriculum so that the TSS course is no longer a required component. FTA recognizes the value of the TSS course and will continue to offer it, but concurs that security is not within the general scope of training required to implement 49 U.S.C. 5329(c)(1) safety oversight requirements. Additionally, FTA has determined that the course objectives for the 2-hour online "SMS Gap course" training are now included in the online "SMS Awareness" course and the "SMS Principles for Transit" course; therefore, it is no longer a requirement.

For clarity, FTA is renaming the "SMS Principles for Rail Transit" to "SMS Principles for Transit" in order to reflect its broader applicability across the industry. In addition, the "SMS Principles for SSO Programs" course is currently under development and is not expected to be available by the effective date of this rule; therefore, participants will have three years from the course's date of availability to complete it. The curriculum for the PTSCTP is revised accordingly and appears as Appendix A to this part and is no longer referred to as the Reference Document as noted in the NPRM. FTA will continue to evaluate the effectiveness of the PTSCTP requirements and should FTA determine revisions are warranted, FTA will seek public comment prior to doing so.

IV. Revised Regulatory Evaluation

Before MAP-21, FTA funded and supported a wide variety of safety training at no direct cost to the transit industry and participants engaged in the training on a voluntary basis. Subsequently, MAP-21 mandated that FTA develop an interim training safety certification program to enhance the technical qualifications of designated personnel directly responsible for safety oversight of public transportation systems in advance of a final rule for the Public Transportation Safety Certification Training Program. FTA noted that the interim program requirements were a condition of receiving Federal grant funding under sections 5307, 5311, and 5329 of title 49, United States Code. Although the interim program was not promulgated as a rulemaking, pursuant to 49 U.S.C. 5334(k), FTA sought public comment on the interim provisions. It was noted that most of a participant's cost in the interim program would be an eligible expenditure of Federal financial assistance provided under sections 5307, 5311, and 5329 grants and no cost benefit analysis was conducted. FTA will now incorporate many components of the interim program in the final rule for the PTSCTP; however, with a lessened regulatory burden for required participants.

The regulatory analyses below include the cost estimates for the final rule as required by Executive Order 12866 (Regulatory Planning and Review), using pre-MAP-21 estimates as the base line with revisions based on comments to the NPRM. The analysis also includes a deregulatory action cost estimate as required by Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs), as the cost of the final rule is less than the cost of the interim rule.

For the initial analysis to assess the costs for the PTSCTP, FTA first reviewed data from the Transportation Safety Institute (TSI) the organization that provides FTA sponsored training for transit grantees and stakeholders. Using the TSI attendance data for the transit safety courses and knowledge of how SSOAs and rail transit agencies are organized, FTA developed a maximum and minimum number of personnel, to include employees and contractors that would be affected by the PTSCTP. FTA also reviewed the number of FTA personnel who participate in safety audits and examinations and determined the number of FTA personnel that would be required to undergo some level of training and certification.

In developing annual costs for personnel that would attend the PTSCTP, FTA assumed a minimum and maximum case scenario. Under the minimum case scenario, it is assumed that no additional staff will take the TSSP other than the ones who are already doing so. The TSI data prior to MAP-21 shows that on average 250 individuals attended the four TSSF courses, ranging from 175 attendees for transit rail incident investigations to 345 attendees for the transit rail system safety course. Given the total number of transit and SSOA entities, there were between two to three individuals per agency on average attending the courses already. The only additional training taken would be for the Safety Management System curriculum. In addition, to meet the requirements of this rule, the agencies would need to apply for certification for courses attended at TSI or at another venue and to maintain records of the training completed. The cost of the additional effort is included below.

The maximum case scenario assumes a higher number of attendees than the current practice and assumes no prior completion of safety training. This scenario is being presented to show the cost of the rule if the level of attendance increases due to the publication of this final rule and if the training already taken by individuals does not satisfy the TSSP course requirements under this final rule.

FTA notes that this analysis includes only the costs that could be quantified, which are those costs associated with the training, certification and record keeping. It does not reflect costs associated with any additional countermeasures that better trained personnel might take to increase safety that they would not have identified prior to taking the training.

The initial cost-benefit analysis was provided in the NPRM for public comment. Several commenters asked if additional Federal funding would be available to pay for the training and asked why additional funding is not available for RTAs, but available to

FTA Response: Funding determinations are made by Congress through statutory parameters for Chapter 53 recipients, including RTAs. In this instance, the training costs associated with the PTSCTP are an eligible expense for the Federal grants available to RTAs. However, Congress has provided funding for the State Safety Oversight program to eliminate the conflict of interest inherent between SSOAs and RTAs when RTAs provide funding to SSOAs that provide oversight

of these RTAs. Furthermore, the incremental cost per RTA is not expected to be significant considering many agency employees already undertake or have completed most of the required courses. Additionally, much of the new SMS training is available online at no additional monetary cost, except staff time.

Several commenters noted the additional cost burden of travel to meet the training requirements if the courses are not available locally or online. One commenter indicated that its costs could be approximately \$3,000 per course per employee to take the TSSP courses. It was also mentioned that employees will be away from their jobs to attend the training and this will result in loss of productivity. One commenter requested that costs be shown on a per capita basis for each recipient instead of the aggregate estimate reflected in the NPRM.

FTA Response: FTA does not expect agencies to incur significant additional travel costs since much of the SMS training is available online and FTA plans to increase its capacity to deliver training locally, which will provide more opportunities to attend without incurring additional expenses. FTA will also make training schedules available earlier to support improved scheduling. However, recognizing there may be occasions where travel may be required; FTA is including estimated travel costs in the revised assumptions for this rule.

Regarding cost estimates (labor cost), the assumptions herein reflect the loss of individual productivity to attend the training. It is anticipated that this cost will be regained through benefits from improved safety performance of the agencies. However, FTA notes that it is a challenge to project costs per recipient because each recipient is responsible for identifying which of its safety oversight personnel will be required participants. Furthermore, participants will have varying degrees of requirements to fulfill depending on their prior TSSP participation.

To determine aggregate costs, FTA made the following revisions to its analysis. FTA is now using the hourly wage rate for a transit manager from the 2016 Bureau of Labor Statistics to represent the average cost for personnel attending the training. The wage rate is adjusted to account for benefits and other employee compensation cost to reflect the full agency cost. The revised estimate also considers travel costs, assuming that 5 percent of required participants may not be able to attend courses locally. Furthermore, the Transit System Security (TSS) is eliminated, thus reducing the required

training from 140 hours over three years to 104 hours over the same period. The TSS training remains available for participants, but is optional.

Additionally, FTA has eliminated the 2-hour SMS Gap course, which reduces the number of SMS training from 41 hours over three years to 39 hours over the same period. This results in lower personnel training costs relative to PTSCTP compliance costs, but does not significantly reduce FTA's cost for providing the training.

For the minimum case, we continued with the assumption that all designated

personnel under this program had already completed the required courses and would require only the SMS portion of the curriculum. This assumption is supported given the popularity of the TSSP within the industry. It is supported further by the level of voluntary participation of transit industry personnel obtained from current graduation/attendance data at TSI.

For the maximum case, we continue with the assumption that no one subject to the rule has a TSSP Certificate. In this case, all designated personnel would have to take and complete both the TSSP (minus the TSS course) and SMS coursework over the allotted three-year period. The table below shows the estimated counts used in our analysis. To simplify the analysis, we assume that the total designated personnel under this rule would undertake one-third of the total coursework each year. The required training would be completed over a period of three years.

ESTIMATED UNIVERSE OF POTENTIAL SSOA, RAIL TRANSIT AGENCY, AND FTA PERSONNEL

| | Minimum | Maximum |
|----------------|-----------------|------------------|
| SSOA Personnel | 70 200 40 | 120 340 40 |
| Total | 310 | 500 |

Next, we determined the training by course that would be required of each person within the scope of the PTSCTP.

TSSP Curriculum

The TSSP consists of three courses. ¹ The Table below lists the courses and duration.

TSSP Coursework Required

[Completed within a 3 year period]

| TSSP courses | Hours |
|--------------------|---------------------|
| Rail System Safety | 36 36 0 32 |
| Total | 104 |

SMS Curriculum

The SMS curriculum consists of two in-person courses and two online

training sessions. While SSO personnel will be required to now take 39 hours of total training, rail transit agency

personnel will no longer be required to take the 2 hour SMS Gap course.

SMS COURSEWORK—IN-CLASS AND ONLINE REQUIRED

[Completed within a 3 year period]

| SMS courses | Hours |
|---|-------------------------|
| SMS Awareness Safety Assurance SMS Gap (no longer mandatory) SMS Principles for Transit SMS Principles for SSO Programs | 1 2 0 20 16 |
| Total | 39 |

Wage Rates

An average wage rate of \$86.11 is assumed for those taking training under

¹ The TSSP has two tracks, one for rail and one for bus-based transport. Since the PTSCTP is optional for bus-based transit we do not address those costs or benefits in the analysis.

this program, based on 2016 Bureau of Labor Statistics data on average wages for transit managers, including an adjustment for benefits and other employee compensation costs.² Using this wage assumption, we have revised

² Bureau of Labor Statistics, Occupational Employment Statistics for Urban Transit Systems (485100), General and Operations Managers (11– 1021), May 2014. The average hourly wage of

^{55.18} was multiplied by a benefits adjustment of 1.56.

Lower Bound and Upper Bound costs for attendance as depicted in the table below.

for attendance as depicted in the table below.

ANNUAL COSTS FOR ATTENDANCE OF SSOA, RAIL TRANSIT AGENCY, AND FTA PERSONNEL WITHIN A 3-YEAR PERIOD

| | Number of personnel | Hourly rate | Training time (hours) | Annual attendance costs (total costs divided by 3) |
|--|---------------------|------------------|-----------------------|---|
| Lower Bound Mandatory Cost/YearUpper Bound Mandatory Cost/Year | 310 500 | \$86.11 86.11 | 39 SSOA-FTA, 23 RTA | \$255,174 1,896,156 |

In addition to the training requirements for certification, RTA personnel are required to attend one hour of training every two years to maintain the certification of their own choosing. This would add an ongoing annual cost of \$13,347 for the minimum case scenario and just over \$21,527 for the maximum case scenario.

Travel Costs

To allow for situations where staff are unable to attend local training, travel costs are estimated. Based on current air and hotel rates, and hourly wage rate of \$86.11, transportation cost of \$600 and lodging and meals of \$250 per day and travel time cost of \$690 for eight hours of travel time is estimated. It is unknown how many participants would need to travel to attend training.

However, training is frequently provided by FTA across the country and agencies have three years in which to complete the training; therefore, only a small percentage are expected to travel. FTA estimated the cost assuming that only 5 percent of the required participants may travel to another location to attend a course out of state. The table below shows the annual travel costs for attending safety training courses.

ANNUAL TRAVEL COST TO ATTEND THE TRAINING

| Personnel required to travel to attend training | Number of personnel | Travel cost per person | Total annual travel cost |
|---|---------------------|------------------------|--------------------------|
| Lower Bound (5%) | 4 | \$4,078 | \$18,282 |
| | 8 | 11,694 | 89,852 |

Administrative Costs

To comply with the requirements of the final rule, SSOAs and RTAs will incur time to designate appropriate staff for training; seek evaluation for safety training previously taken to ensure compliance with FTA requirements; keep records of training completed and ensure certification. The total annual costs of these activities are estimated to be \$212,735. The same cost estimate is applied to the lower and upper bound, although the cost would be higher for the lower bound since the course evaluation will not be needed if all personnel attend the new training, as assumed for the upper bound estimates.

Next, we assessed costs associated with developing, managing, and

administering the coursework for the PTSCTP. First, we reviewed the course catalog for TSI and determined the percentage of courses required by the PTSCTP of the total courses offered—a little more than one-fourth (six courses plus three online courses out of 21 total courses or about 29 percent) of the total course offerings would be required of the combined TSSP/SMS training under this rule. Furthermore, of the total days of coursework offered by TSI, 30 percent were attributable to the TSSP/SMS coursework. To be conservative, we used a 30 percent weighting for allocating fixed costs and allocated full costs where we were able to identify costs resulting from the TSSP and/or SMS training components. Using data from FTA's budget for TSI, the cost for

the administration of courses, contract costs, and costs for the development of new coursework, we developed the program costs. We factored no facility costs as regional transit agencies or FTA Regional Offices host courses. Lastly, no tuition fees are associated with taking the coursework for public agency employees, other than a small fee for course materials.

The total cost for FTA to deliver the courses required under PTSTCP was about \$1.4 million. However, since the TSSP training was previously provided prior to MAP–21, this cost is excluded from estimating the incremental cost of this rule. SMS training courses have been more recently developed to support safety goals, thus that is the only cost included here.

TSI PROGRAM COSTS ASSOCIATED WITH TSSP AND SMS COURSEWORK

| Contract Services Equipment, Supplies, Other* Travel (Other than Course Delivery)* Course Delivery Indirect at 19% | \$211,600 33,291 7,886 186,744 106,332 |
|--|--|
| Total Program | 665,974 |

^{*} Weighted Cost Allocation.

The total annual cost of providing the SMS training is estimated to be \$665,974 per year. Table below shows

the total annual cost of the final rule over the first three years.

TOTAL ANNUAL COSTS FOR THE PTSCTP OVER A 3 YEAR CERTIFICATION PERIOD

| | SSOA and RTA costs | TSI costs | Total costs |
|---------------------|-----------------------|-----------|-------------|
| Aggregate COSTS MIN | \$486,191 | \$665,974 | \$1,152,166 |
| | 2,198,743 | 665,974 | 2,864,717 |

After completing the required training over the three-year period, RTA staff are required to complete an hour of refresher training every two years. These costs will incur beyond the three-year period discussed above. Similarly, any new personnel joining the agencies would be required to complete the training. To estimate the cost of training for the new staff, we used the rate of separations published in the U.S. Bureau of Labor Statistics monthly report, Job Opening and Labor Turnover. Using the rate of separation (quits, layoffs and discharges) of 1.8 percent for State and local government employees, excluding education, over the period September 2016 to September 2017, we estimated the number of staff requiring training after the third year. The annual cost of the refresher training and the new personnel is about \$34,000 for the minimum case and \$83,000 for the maximum case beyond the first three years. Using a ten year period of analysis, the total present value cost of the final rule is \$8.4 million at 7 percent discount rate for the minimum case scenario and \$3.4 million at 7 percent discount rate for maximum scenario. At the 7 percent discount rate, the annualized costs are \$0.48 million and \$1.2 million for the minimum and maximum scenario. The annualized cost for the minimum and the maximum case, at 3 percent discount rate is \$0.42 million and \$1.03 million respectively.

Potential Benefits

Since the interim provisions have been in effect for only a short time, we were unable to generate any estimate of their benefits. Thus, to assess the benefits for the PTSCTP, we considered how the training required in this rulemaking could strengthen the State Safety Oversight program, since better trained personnel would be expected to take actions that are likely to lead to decreased safety risks.

While the TSSP has been available for some time, it was an optional certification that many SSOA, rail, and bus safety oversight personnel sought out of self-initiative. With the delineation of a mandatory pool of safety oversight employees, FTA hopes to unify and harmonize the provision of safety-related activities across SSOAs and rail transit agencies. In this way, this pool of employees will gain knowledge to identify and control hazards with the ultimate goal of decreasing incidents. Additionally, FTA expects that the codification of the PTSCTP will help promote a safety culture within the transit industry. This safety culture should help instill a transit agency-wide appreciation for shared goals, shared beliefs, best practices, and positive and vigilant attitudes towards safety.

It may be difficult to quantify the effects of a positive safety culture, as a safety culture will develop over time. Characteristics of a positive safety culture include: Actively seeking out

information on hazards; employee training; information exchanges; and understanding that responsibility for safety is shared. While the returns on investment in training should be fairly quick, establishing, promoting, and increasing safety in an industry that is already very safe is difficult to predict with any certainty.

Comparison of the Cost of the Final Rule With the Interim Provisions

On February 27, 2015, FTA issued a notice of interim safety certification training program provisions for Federal and State Safety Oversight Agency personnel and their contractor support who conduct safety audits and examinations of public transportation systems not otherwise regulated by another Federal agency. The proposed final rule will replace the provisions outlined in the interim notice. The training program outlined in this final rule will eliminate two requirements; the Transit System Security course and the SMS Gap online course. Rail security is not under FTA's authority, so it is not a training requirement mandated by 49 U.S.C. 5329. The SMS Gap course requirement is eliminated because many of the elements of this course are included in the SMS Principles for Transit. This reduces the burden of the final rule compared to the interim provisions enacted in February 2015. The table below shows the annual cost of the Interim Rule and the Final

PUBLIC TRANSPORTATION SAFETY CERTIFICATION TRAINING PROGRAM—HOURS AND COST DECREASE

| Training requirements | Interim rule | Final rule | Difference between rules |
|---|--|---|-----------------------------|
| Safety Management System (SMS) Gap Course (Hours) ³ | ⁴ 41 140 | 39 104 | -2 -36 |
| Total Minimum Case Scenario Present Value Cost (7%) Maximum Case Scenario Present Value Cost (7%) Minimum Case Scenario Mandatory Annualized Cost (7%) Maximum Case Scenario Annualized Cost ((7%)) | 181 \$3,447,233 \$10,022,279 \$490,808 \$1,426,947 | 143 \$3,395,753 \$8,436,102 \$483,479 \$1,201,111 | -\$1,586,177 -\$7,330 |

Over a ten-year period, the final rule reduces the cost of the rule by \$51,480 at the minimum case scenario and \$1.6 million at the maximum case scenario using a discount rate of 7 percent. The annualized cost reductions of the final rule are \$7,330 for the minimum case and \$225,836 for the maximum case, using a 7 percent discount rate, resulting in a net benefit for the training participants. The reduced training requirements will not hinder the effectiveness of the safety training program since the participants will receive much of the relevant content through other courses or by other requirements, not covered under this rule certification requirements.

V. Regulatory Analyses and Notices

Regulatory Flexibility Act and Executive Order 13272

This rule was developed in accordance with Executive Order 13272 (Proper Consideration of Small Entities in Agency rulemaking) and DOT's policies and procedures to promote compliance with the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) which requires an agency to review regulations to assess the impact on small entities. In compliance with the Regulatory Flexibility Act, FTA has evaluated the likely effects of the

proposals set forth in this rule on small entities. This rule will apply to recipients of public transportation grants under 49 U.S.C. Chapter 53. Section 5329(e)(6) permits recipients of rural and urbanized area formula funds to use Federal funds to cover up to 80 percent of the PTSCTP costs. Additionally, FTA believes many of the PTSCPT participants will be eligible to receive credit for prior safety training which will further reduce the cost and impact associated with this rulemaking. For these reasons, FTA certifies that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

Executive Orders 12866 and 13563 direct Federal agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits—including potential economic, environmental, public health and safety effects, distributive impacts, and equity. Executive Order 13563 emphasizes the importance of quantifying both costs

and benefits, reducing costs, harmonizing rules, and promoting flexibility.

FTA has determined this rulemaking is not a significant regulatory action within the meaning of Executive Order 12866, Executive Order 13563, and the U.S. Department of Transportation's regulatory policies and procedures (DOT Order 2100.5 dated May 22, 1980, 44 FR 11034, Feb. 26, 1979). FTA has determined that this rulemaking is not economically significant. The proposals set forth in this rulemaking will not result in an effect on the economy of \$100 million or more. The requirements set forth in the rulemaking will not adversely affect the economy, interfere with actions taken or planned by other agencies, or generally alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Executive Order 13771

As indicated in the cost-benefit analysis above and the summary chart below, this final rule is considered an Executive Order 13771 deregulatory action because it reduces the cost of complying with FTA's Interim Safety Certification and Training Program (interim program) requirements promulgated in accordance with 49 U.S.C. 5329(c)(2) (see 80 FR 10619).

| Training requirements | Interim rule | Final rule | Difference between rules |
|--|--------------|-------------|-----------------------------|
| Safety Management System (SMS) Course (Hours) 6 | 741 | 39 | -2 |
| Transit Safety and Security (TSS) Course (days) ⁸ | 140 | 104 | - 36 |
| Total | 181 | 143 | -38 |
| Minimum Case Scenario Present Value Cost (7%) | \$3,447,233 | \$3,395,753 | - \$51,480 |
| Maximum Case Scenario Present Value Cost (7%) | \$10,022,279 | \$8,436,102 | -\$1,586,177 |
| Minimum Case Scenario Mandatory Annualized Cost (7%) | \$490,808 | \$483,479 | -\$7,330 |
| Maximum Case Scenario Annualized Cost ((7%)) | \$1,426,947 | \$1,201,111 | - \$225,836 |

Unfunded Mandates Reform Act of 1995

This rulemaking would 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 cost of training to comply with this rule is an eligible expenditure of Federal financial assistance provided to recipients under 49 U.S.C. Chapter 53. This rulemaking will not result in the expenditure by State, local, and tribal governments, in the aggregate, or

by the private sector, of \$155 million or more in any one year.

Executive Order 12372 (Intergovernmental Review)

The regulations effectuating Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities were applied during this rulemaking. Executive Order 13132 (Federalism)

This rulemaking has been analyzed in accordance with the principles and criteria established by Executive Order 13132, and FTA has determined that this rulemaking would not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. FTA has also concluded that this rulemaking would not preempt any State law or State regulation or affect the States' abilities to discharge

³ FTA eliminated the "SMS Gap" course as part of the mandatory curriculum for the final rule since the "SMS Principles for Transit" course includes similar objectives.

⁴The number of hours of training for the SMS Principles for Rail Transit course ("SMS Principles for Transit" in final rule) was incorrectly cited in the interim rule as 16 hours instead of 20 hours, this has been corrected in the final rule.

⁵ Based on public comment FTA eliminated the TSS course as part of the mandatory curriculum for the final rule.

⁶ FTA eliminated the "SMS Gap" course as part of the mandatory curriculum for the final rule since the "SMS Principles for Transit" course includes similar objectives.

⁷ The number of hours of training for the SMS Principles for Rail Transit course ("SMS Principles for Transit" in final rule) was incorrectly cited in the interim rule as 16 hours instead of 20 hours, this has been corrected in the final rule.

⁸ Based on public comment FTA eliminated the TSS course as part of the mandatory curriculum for the final rule.

traditional State governmental functions.

Paperwork Reduction Act

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.; "PRA") and the OMB regulation at 5 CFR 1320.8(d), FTA is seeking approval from OMB for the Information Collection Request abstracted below. In order to comply with the requirements to implement the PTSCTP in accordance with 49 U.S.C. 5329(c)(1), this rulemaking requires recipients to provide information to FTA regarding the participation of their respective designated personnel as abstracted below. Designated personnel would provide enrollment information, periodically update compliance with PTSCTP training requirements, and where applicable, submit supporting documentation of prior training for credit towards PTSCTP training requirements. All recipients of mandatory PTSCTP requirements would annually certify compliance with the PTSCTP requirements. Additionally, SSOAs would be required to develop annual technical training plans for FTA approval. The plans would support the SSOA requirement to demonstrate that applicable SSOA personnel are qualified to perform safety audits and examinations.

The information collection would be different for each type of recipient (Federal government personnel, Federal contractors, SSOAs and their contractors, and rail transit agencies). Therefore, the paperwork burden would vary. For example, the burden on SSOAs would be proportionate to the number of rail transit agencies within that State, and the size and complexity of those rail transit systems. This would affect the number of personnel designated for participation. FTA proposes to bear the cost associated with the development and maintenance of the website.

Type of Review: OMB Clearance. New information collection request.

Respondents: Currently there are 30 States with 60 rail fixed guideway public transportation systems in engineering, construction, and operations. The PRA estimate is based on participation in the PTSCTP by a total of 30 States and 60 rail transit agencies. In addition, we estimate participation by 35–45 SSOA contractors and approximately 30 Federal personnel and contractors.

Frequency: Information will be collected through the website on an ongoing basis throughout the year. Participants must complete training requirements within 3 years and

refresher training every 2 years. Certification of compliance will be required annually.

Estimated Total Annual Burden Hours: In the first year of the program, we estimate a total burden of between 5,209 (minimum) and 5,909 (maximum) hours, depending on how many individuals are required to participate. Annually, each SSOA would devote between 88–91 hours to information collection activities including the development and submission of training plans to FTA. SSOA contractors would devote approximately 140-180 hours to information collection activities. These activities would have a combined total of 2,780-2,920 hours, depending on how many individuals are required to participate. The mandatory participants affected by 49 U.S.C. 5329(c)(1) and today's rulemaking include 60 rail fixed guideway public transportation systems which would spend an estimated annual total of between 2,060 (minimum) and 2,620 (maximum) hours on information collection activities in the first year, or approximately 34-44 hours each. Finally, FTA is expected to expend approximately 249 hours in furtherance of the PTSCTP in the first year, and Federal contractors will spend an estimated four (4) hours each, for a combined total of approximately 369 hours in the first year. For this rule, OMB has issued control number 2132-0578.

National Environmental Policy Act

The National Environmental Policy Act of 1969 (42 U.S.C. 4321, et seq.) requires Federal agencies to analyze the potential environmental effects of their proposed actions in the form of a categorical exclusion, environmental assessment, or environmental impact statement. This rulemaking is categorically excluded under FTA's environmental impact procedure at 23 CFR 771.118(c)(4), pertaining to planning and administrative activities that do not involve or lead directly to construction, such as the promulgation of rules, regulations, and directives. FTA has determined that no unusual circumstances exist in this instance, and that a categorical exclusion is appropriate for this rulemaking.

Executive Order 12630 (Taking of Private Property)

This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630.

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

Executive Order 12898 directs every Federal agency to make environmental justice part of its mission by identifying and addressing the effects of all programs, policies, and activities on minority populations and low-income populations. The USDOT environmental justice initiatives accomplish this goal by involving the potentially affected public in developing transportation projects that fit harmoniously within their communities without compromising safety or mobility. Additionally, FTA has issued a program circular addressing environmental justice in public transportation, C 4703.1, Environmental Justice Policy Guidance for Federal Transit Administration Recipients. This circular provides a framework for FTA grantees as they integrate principles of environmental justice into their transit decision-making processes. The Circular includes recommendations for State Departments of Transportation, Metropolitan Planning Organizations, and public transportation systems on (1) How to fully engage environmental justice populations in the transportation decision-making process; (2) How to determine whether environmental justice populations would be subjected to disproportionately high and adverse human health or environmental effects of a public transportation project, policy, or activity; and (3) How to avoid, minimize, or mitigate these effects.

Executive Order 12988 (Civil Justice Reform)

This action meets the applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988 to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

FTA has analyzed this rulemaking under Executive Order 13045. FTA certifies that this rule will not cause an environmental risk to health or safety that may disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

FTA has analyzed this rulemaking under Executive Order 13175 and finds that the action will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; will not preempt tribal laws; and will not impose any new

consultation requirements on Indian tribal governments. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

FTA has analyzed this rulemaking under Executive Order 13211 and has determined that this action is not a significant energy action under the Executive Order, given that the action is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Privacy Act

In accordance with 5 U.S.C. 553(c), U.S. DOT solicits comments from the public to better inform its rulemaking process. U.S. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Statutory/Legal Authority for This Rulemaking

This rulemaking is issued under the authority of 49 U.S.C. 5329(c)(1) as amended, which requires the Secretary of Transportation to prescribe a public transportation safety certification training program for Federal and State employees, and other designated personnel, who conduct safety audits and examinations of public transportation systems and employees of public transportation agencies directly responsible for safety oversight. The Secretary is authorized to issue regulations to carry out the general provisions of this statutory requirement pursuant to 49 U.S.C. 5329(f)(7).

Regulation Identification Number

A regulation identification 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 set forth in the heading can be used to crossreference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 672

Mass transportation, Reporting and recordkeeping requirements, Safety, Transportation.

K. Jane Williams,

Acting Administrator.

■ For the reasons set forth in the preamble, and under the authority of 49 U.S.C. 5329(c), 5329(f), and the

delegation of authority at 49 CFR 1.91, FTA hereby amends Chapter VI of Title 49, Code of Federal Regulations, by adding part 672 to read as follows:

PART 672—PUBLIC TRANSPORTATION SAFETY **CERTIFICATION TRAINING PROGRAM**

Subpart A—General Provisions

672.1 Purpose.

672.3Scope and applicability.

672.5 Definitions.

Subpart B—Training Requirements

672.11 Designated personnel who conduct safety audits and examinations.

672.13 Designated personnel of public transportation agencies.

672.15 Evaluation of prior certification and training.

Subpart C—Administrative Requirements

672.21 Records.

672.23 Availability of records.

Subpart D—Compliance and Certification Requirements

672.31 Requirement to certify compliance. Appendix A to Part 672—Public Transportation Safety Certification

Training Program

Authority: 49 U.S.C. 5329(c) and (f), and 49 CFR 1.91.

Subpart A—General Provisions

§ 672.1 Purpose.

- (a) This part implements a uniform safety certification training curriculum and requirements to enhance the technical proficiency of individuals who conduct safety audits and examinations of public transportation systems operated by public transportation agencies and those who are directly responsible for safety oversight of public transportation agencies.
- (b) This part does not preempt any safety certification training requirements required by a State for public transportation agencies within its jurisdiction.

§ 672.3 Scope and applicability.

- (a) In general, this part applies to all recipients of Federal financial assistance under 49 U.S.C. chapter 53.
- (b) The mandatory requirements of this part will apply only to State Safety Oversight Agency personnel and contractors that conduct safety audits and examinations of rail fixed guideway public transportation systems, and designated personnel and contractors who are directly responsible for the safety oversight of a recipient's rail fixed guideway public transportation systems.

(c) Other FTA recipients may participate voluntarily in accordance with this part.

§ 672.5 Definitions.

As used in this part: Administrator means the Federal Transit Administrator or the Administrator's designee.

Contractor means an entity that performs tasks on behalf of FTA, a State Safety Oversight Agency, or public transportation agency through contract or other agreement.

Designated personnel means: (1) Employees and contractors identified by a recipient whose job function is directly responsible for safety oversight of the public transportation system of the public transportation agency; or

(2) Employees and contractors of a State Safety Oversight Agency whose job function requires them to conduct safety audits and examinations of the rail fixed guideway public transportation systems subject to the jurisdiction of the agency.

Directly responsible for safety oversight means public transportation agency personnel whose primary job function includes the development, implementation and review of the agency's safety plan, and/or the SSOA requirements for the rail fixed guideway public transportation system pursuant to 49 CFR parts 659 or 674.

Examination means a process for gathering or analyzing facts or information related to the safety of a public transportation system.

FTA means the Federal Transit Administration.

Public transportation agency means an entity that provides public transportation service as defined in 49 U.S.C. 5302 and that has one or more modes of service not subject to the safety oversight requirements of another Federal agency.

Rail fixed guideway public transportation system means any fixed guideway system as defined in § 674.7 of this chapter.

Recipient means a State or local governmental authority, or any other operator of a public transportation system receiving financial assistance under 49 U.S.C. chapter 53.

Safety audit means a review or analysis of safety records and related materials, including, but not limited to, those related to financial accounts.

State means a State of the United States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, and the Virgin Islands.

State Safety Oversight Agency (SSOA) means an agency established by a State

that meets the requirements and performs the functions specified by 49 U.S.C. 5329(e) and the regulations set forth in 49 CFR parts 659 and 674.

Subpart B—Training Requirements

§ 672.11 Designated personnel who conduct safety audits and examinations.

(a) Each SSOA shall designate its personnel and contractors who conduct safety audits and examinations of public transportation systems, including appropriate managers and supervisors of such personnel, that must comply with the applicable training requirements of

Appendix A to this part.

(b) Designated personnel shall complete applicable training requirements of this part within three (3) years of their initial designation. Thereafter, refresher training shall be completed every two (2) years. The SSOA shall determine refresher training requirements which must include, at a minimum, one (1) hour of safety oversight training.

§ 672.13 Designated personnel of public transportation agencies.

(a) Each recipient that operates a rail fixed guideway public transportation system shall designate its personnel and contractors who are directly responsible for safety oversight and ensure their compliance with the applicable training requirements set forth in Appendix A to this part.

(b) Each recipient that operates a bus or other public transportation system not subject to the safety oversight of another Federal agency may designate its personnel who are directly responsible for safety oversight to participate in the applicable training requirements as set forth in Appendix A

to this part.

(c) Personnel designated under paragraph (a) of this section shall complete applicable training requirements of this part within three (3) years of their initial designation. Thereafter, refresher training shall be completed every two (2) years. The recipient shall determine refresher training requirements which must include, at a minimum, one (1) hour of safety oversight training.

§ 672.15 Evaluation of prior certification and training.

- (a) Designated personnel subject to this part may request that FTA evaluate safety training or certification previously obtained from another entity to determine if the training satisfies an applicable training requirement of this part.
- (b) Designated personnel must provide FTA with an official transcript

or certificate of the training, a description of the curriculum and competencies obtained, and a brief statement detailing how the training or certification satisfies the applicable requirements of this part.

(c) FTA will evaluate the submission and determine if a training requirement of this part may be waived. If a waiver is granted, designated personnel are responsible for completing all other applicable requirements of this part.

Subpart C—Administrative Requirements.

§ 672.21 Records.

- (a) General requirement. Each recipient shall ensure that its designated personnel are enrolled in the PTSCTP. Each recipient shall ensure that designated personnel update their individual training record as he or she completes the applicable training requirements of this part.
- (b) SSOA requirement. Each SSOA shall retain a record of the technical training completed by its designated personnel in accordance with the technical training requirements of Appendix A to this part. Such records shall be retained by the SSOA for at least five (5) years from the date the record is created.

§ 672.23 Availability of records.

- (a) Except as required by law, or expressly authorized or required by this part, a recipient may not release information pertaining to designated personnel that is required by this part without the written consent of the designated personnel.
- (b) Designated personnel are entitled, upon written request to the recipient, to obtain copies of any records pertaining to his or her training required by this part. The recipient shall promptly provide the records requested by designated personnel and access shall not be contingent upon the recipient's receipt of payment for the production of such records.
- (c) A recipient shall permit access to all facilities utilized and records compiled in accordance with the requirements of this part to the Secretary of Transportation, the Federal Transit Administration, or any State agency with jurisdiction over public transportation safety oversight of the recipient.
- (d) When requested by the National Transportation Safety Board as part of an accident investigation, a recipient shall disclose information related to the training of designated personnel.

Subpart D—Compliance and **Certification Requirements**

§ 672.31 Requirement to certify compliance.

- (a) A recipient of FTA financial assistance described in § 672.3(b) shall annually certify compliance with this part in accordance with FTA's procedures for annual grant certification and assurances.
- (b) A certification must be authorized by the recipient's governing board or other authorizing official, and must be signed by a party specifically authorized to do so.

Appendix A to Part 672—Public **Transportation Safety Certification Training Program**

A. Required Curriculum Over a Three-Year Period

- (1) FTA/SSOA personnel and contractor support, and public transportation agency personnel with direct responsibility for safety oversight of rail fixed guideway public transportation systems:
- (a) One (1) hour course on SMS Awareness—e-learning delivery (all required participants)
- (b) Two (2) hour courses on Safety Assurance—e-learning delivery (all required participants)
- (c) Twenty (20) hours on SMS Principles for Transit (all required participants)
- (d) Sixteen (16) hours on SMS Principles for SSO Programs (FTA/SSOA/contractor support personnel only)
- (e) TSSP curriculum (minus Transit System Security (TSS) course) (all required participants-credit will be provided if participant has a Course Completion Certificate of previously taken TSSP courses)
- (i) Rail System Safety (36 hours)
- (ii) Effectively Managing Transit Emergencies (32 hours)
 - (iii) Rail Incident Investigation (36 hours)
- (2) FTA/SSOA/contractor support personnel (technical training component):
- (a) Each SSOA shall develop a technical training plan for designated personnel and contractor support personnel who perform safety audits and examinations. The SSOA will submit its proposed technical training plan to FTA for review and evaluation as part of the SSOA certification program in accordance with 49 U.S.C. 5329(e)(7). This review and approval process will support the consultation required between FTA and SSOAs regarding the staffing and qualification of the SSOAs' employees and other designated personnel in accordance with 49 U.S.C. 5329(e)(3)(D).
- (b) Recognizing that each rail fixed guideway public transportation system has unique characteristics, each SSOA will identify the tasks related to inspections, examinations, and audits, and all activities requiring sign-off, which must be performed by the SSOA to carry out its safety oversight requirements, and identify the skills and knowledge necessary to perform each task at that system. At a minimum, the technical training plan will describe the process for

receiving technical training in the following competency areas appropriate to the specific rail fixed guideway public transportation system(s) for which safety audits and examinations are conducted:

(i) Agency organizational structure

(ii) System Safety Program Plan and Security Program Plan

(iii) Knowledge of agency:

(I) Territory and revenue service schedules

(II) Current bulletins, general orders, and other associated directives that ensure safe operations

(III) Operations and maintenance rule books

(IV) Safety rules

(V) Standard Operating Procedures

(VI) Roadway Worker Protection

(VII) Employee Hours of Service and Fatigue Management program

(VIII) Employee Observation and Testing Program (Efficiency Testing)

(IX) Employee training and certification requirements

(X) Vehicle inspection and maintenance programs, schedules and records

(XI) Track inspection and maintenance programs, schedules and records

(XII) Tunnels, bridges, and other structures inspection and maintenance programs, schedules and records

(XIII) Traction power (substation, overhead catenary system, and third rail), load dispatching, inspection and maintenance programs, schedules and records

(XIV) Signal and train control inspection and maintenance programs, schedules and

records

(c) The SSOA will determine the length of time for the technical training based on the skill level of the designated personnel relative to the applicable rail transit agency(s). FTA will provide a template as requested to assist the SSOA with preparing and monitoring its technical training plan

and will provide technical assistance as requested. Each SSOA technical training plan that is submitted to FTA for review will:

(i) Require designated personnel to successfully:

(I) Complete training that covers the skills and knowledge needed to effectively perform the tasks.

(II) Pass a written and/or oral examination covering the skills and knowledge required for the designated personnel to effectively perform his or her tasks.

(III) Demonstrate hands-on capability to perform his or her tasks to the satisfaction of the appropriate SSOA supervisor or designated instructor.

(ii) Establish equivalencies or written and oral examinations to allow designated personnel to demonstrate that they possess the skill and qualification required to perform their tasks.

(iii) Require biennial refresher training to maintain technical skills and abilities which includes classroom and hands-on training, as well as testing. Observation and evaluation of actual performance of duties may be used to meet the hands-on portion of this requirement, provided that such testing is documented.

(iv) Require that training records be maintained to demonstrate the current qualification status of designated personnel assigned to carry out the oversight program. Records may be maintained either electronically or in writing and must be provided to FTA upon request.

(v) Records must include the following information concerning each designated personnel:

(I) Name;

(II) The title and date each training course was completed and the proficiency test score(s) where applicable;

(III) The content of each training course successfully completed;

(IV) A description of the designated personnel's hands-on performance applying the skills and knowledge required to perform the tasks that the employee will be responsible for performing and the factual basis supporting the determination;

(V) The tasks the designated personnel are deemed qualified to perform; and

(VI) Provide the date that the designated personnel's status as qualified to perform the tasks expires, and the date in which biennial refresher training is due.

(vi) Ensure the qualification of contractors performing oversight activities. SSOAs may use demonstrations, previous training and education, and written and oral examinations to determine if contractors possess the skill and qualification required to perform their tasks.

(vii) Periodically assess the effectiveness of the technical training. One method of validation and assessment could be through the use of efficiency tests or periodic review of employee performance.

B. Voluntary Curriculum

Bus transit system personnel with direct safety oversight responsibility and State DOTs overseeing safety programs for subrecipients:

- (a) SMS Awareness—e-learning delivery
- (b) Safety Assurance—e-learning delivery
- (c) SMS Principles for Transit
- (d) Courses offered through the TSSP Certificate (Bus)
- i. Effectively Managing Transit Emergencies
 - ii. Transit Bus System Safety
- iii. Fundamentals of Bus Collision Investigation

[FR Doc. 2018–15168 Filed 7–18–18; 8:45 am]

BILLING CODE P

Proposed Rules

Federal Register

Vol. 83, No. 139

Thursday, July 19, 2018

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0368; Product Identifier 2018-NE-12-AD]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney Division (PW) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Pratt & Whitney Division (PW) PW4074D, PW4077D, PW4084D, PW4090, and PW4090-3 turbofan engines with a low pressure compressor (LPC) fan hub, part number (P/N) 51B821 or P/N 52B521, installed. This proposed AD was prompted by updated low cycle fatigue analysis techniques that indicate certain LPC fan hubs could crack prior to their published life limit. This proposed AD would require repetitive eddy current inspections (ECIs) and fluorescent penetrant inspections (FPIs) for cracks in certain LPC fan hubs and removal of hubs from service that fail inspection. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by September 4, 2018.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the instructions for submitting comments.
 - *Fax:* 202–493–2251.
- Mail: U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

• Hand Delivery: Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06118; phone: 800–565–0140; fax: 860–565–5442. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759

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–2018–0368; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800–647–5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Jo-Ann Theriault, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7105; fax: 781–238–7199; email: jo-ann.theriault@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the ADDRESSES section. Include "Docket No. FAA—2018—0368; Product Identifier 2018—NE—12—AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

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

Discussion

We received information concerning an updated analysis by the engine manufacturer, which indicated certain triple-bore LPC fan hubs installed in high-thrust models of the PW4000-112" series turbofan engine could crack prior to their published life limit. This proposed AD would add additional inspections of affected triple-bore LPC fan hubs until they are removed from service and replaced with a part eligible for installation. This condition, if not addressed, could result in fatigue cracking of the LPC fan hub, uncontained hub failure, damage to the engine, and damage to the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed PW Alert Service Bulletin (ASB) PW4G–112–A72–351, dated February 22, 2018. This PW ASB describes procedures for performing LPC fan hub ECIs and FPIs. 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.

Other Related Service Information

We reviewed PW PW4000 Series 112 Inch Turbofan Engines Cleaning, Inspection and Repair (CIR) Manual, P/N 51A750, Chapter/Section 72–31–07, Inspection/Check-02, Revision No. 76, dated March 15, 2018. The CIR Manual contains additional information regarding FPI and ECI of the LPC fan hub.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require repetitive ECIs and FPIs of the LPC fan hub.

Costs of Compliance

We estimate that this proposed AD affects 32 engines installed on airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

| Action | Labor cost | Parts cost | Cost per product | Cost on U.S. operators |
|---------------------|---|------------|------------------|------------------------|
| Pro-rated part cost | 0 work-hours × \$85 per hour = \$0 | \$288,000 | \$288,000 | \$288,000 |
| | 40 work-hours × \$85 per hour = \$3,400 | 0 | 3,400 | 108,800 |

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

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 airworthiness directive (AD):

Pratt & Whitney Division: Docket No. FAA–2018–0368; Product Identifier 2018–NE–12–AD.

(a) Comments Due Date

We must receive comments by September 4, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Pratt & Whitney Division (PW) PW4074D, PW4077D, PW4084D, PW4090, and PW4090–3 turbofan engines with low-pressure compressor (LPC) fan hub, part number (P/N) 51B821 or P/N 52B521, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by low cycle fatigue analysis techniques, updated by the engine manufacturer, which indicated certain LPC fan hubs could crack prior to their published life limit. We are issuing this AD to prevent failure of the LPC fan hub. The unsafe condition, if not addressed, could result in uncontained hub release, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

- (1) After the effective date of this AD, perform a fluorescent penetrant inspection (FPI) and eddy current inspection (ECI) of the LPC fan hub the next time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last FPI and ECI.
- (2) Thereafter, perform an FPI and an ECI of the LPC fan hub every time the engine is separated at the M-flange and the LPC fan hub has accumulated 2,000 or more flight cycles since the last LPC fan hub ECI and FPI inspections.
- (3) Use the Accomplishment Instructions, Step No. 11, in PW Alert Service Bulletin PW4G-112-A72-351, dated February 22, 2018, to do the eddy current inspections.
- (4) If a crack is found during the inspections required by paragraphs (g)(1) or (2) of this AD, remove the LPC fan hub from service before further flight and replace with a part eligible for installation.

(h) Alternative Methods of Compliance (AMOCs)

- (1) The Manager, ECO Branch, 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 certification office, send it to the attention of the person identified in paragraph (i)(1) of this AD. You may email your request to: ANE-AD-AMOC@ 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.

(i) Related Information

- (1) For more information about this AD, contact Jo-Ann Theriault, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7105; fax: 781–238–7199; email: *jo-ann.theriault@faa.gov*.
- (2) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06118; phone: 800–565–0140; fax: 860–565–5442. You may view this referenced service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759.

Issued in Burlington, Massachusetts, on July 12, 2018.

Robert J. Ganley,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2018–15291 Filed 7–18–18; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0648; Product Identifier 2017-SW-087-AD]

RIN 2120-AA64

Airworthiness Directives; Leonardo S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

summary: We propose to adopt a new airworthiness directive (AD) for Leonardo S.p.A. (Leonardo) Model AB139 and AW139 helicopters. This proposed AD would require replacing screws installed on the left and right main landing gear (MLG) shock absorber assembly. This proposed AD is prompted by a report that some screws may have been manufactured without meeting specifications. The actions of this proposed AD are intended to correct an unsafe condition on these helicopters.

DATES: We must receive comments on this proposed AD by September 17, 2018

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 by searching for and locating Docket No. FAA–2018– 0648; or in person at Docket Operations 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, any comments received, and other information. The street address for Docket Operations (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 rule, contact Leonardo S.p.A. Helicopters, Matteo Ragazzi, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–711756; fax +39–0331–229046; or at http://www.leonardocompany.com/-/bulletins. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT:

David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email david.hatfield@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, has issued EASA AD No. 2016-077, dated April 19, 2016, to correct an unsafe condition for Finmeccanica S.p.A. (previously Agusta) Model AB139 and AW139 helicopters if equipped with kit "Increased Gross Weight 6800 kg" part number (P/N) 4G0000F00111 (kit). EASA advises of a manufacturing issue with the standard screws (P/N NAS1351-5H12P) installed on MLG shock absorber assembly P/N 1652B0000-01. According to EASA, a material analysis shows that the MLG shock absorber screws may have a lower fatigue life than the screws used during the certification fatigue tests. EASA states the affected MLG units have been identified by serial number. EASA also advises that this unsafe condition, if not detected and corrected, could result in failure of the MLG shock absorber, collapse or retraction of the MLG, and subsequent damage to the helicopter and injury to occupants.

To correct this condition, the EASA AD requires replacing each standard screw with a new screw P/N 1652A0001–01 and re-identifying the serial number of each MLG shock absorber assembly that has the new screw installed, and prohibits installing any affected MLG shock absorber assembly unless the screw has been replaced.

FAA's Determination

These helicopters have been approved by the aviation authority of Italy and are approved for operation in the United States. Pursuant to our bilateral agreement with Italy, 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

We reviewed Finmeccanica Bollettino Tecnico No. 139–397, dated April 7, 2016, which contains procedures for replacing the standard screws installed on the left and right MLG assembly and for re-identifying the MLG shock absorber assembly P/N and the MLG assembly S/N.

Proposed AD Requirements

This proposed AD would require replacing each standard screw P/N NAS1351–5H12P with a screw P/N 1652A0001–01 and re-identifying the serial number of the MLG assembly within the following compliance times:

- For MLG assemblies with 26,800 or more landings, within 100 hours timein-service (TIS).
- For MLG assemblies with between 22,000 and 26,799 landings, within 300 hours TIS or before the MLG assembly accumulates 27,200 landings, whichever occurs first.
- For MLG assemblies with less than 22,000 landings, within 1,200 hours TIS or before the MLG assembly accumulates 23,200 landings, whichever occurs first.

This proposed AD would also prohibit installing an MLG assembly on any helicopter unless the screw has been replaced.

Costs of Compliance

We estimate that this proposed AD would affect 111 helicopters of U.S.

We estimate that operators may incur the following costs in order to comply with this proposed AD, based on an average labor rate of \$85 per work-hour. Replacing the screws on the left and right MLG assemblies would require about 16 work-hours and \$200 for parts, for a total cost of \$1,560 per helicopter and \$173,160 for the U.S. fleet.

According to Finmeccanica's service information, some 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 by Finmeccanica. Accordingly, 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, 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):

Leonardo S.p.A.: Docket No. FAA-2018-0648; Product Identifier 2017-SW-087-AD.

(a) Applicability

This AD applies to Leonardo S.p.A. Model AB139 and AW139 helicopters, certificated in any category, with an Increased Gross Weight 6,800 Kg kit part number (P/N) 4G0000F00111, and with a main landing gear (MLG) assembly with a P/N and serial number (S/N) listed in Table 1 to paragraph (a) of this AD installed.

| P/N | S/N |
|---------------------------|---------------------|
| 3G3210V00137 or | 00100 through 01003 |
| 1650B1000-01 (left hand) | 02000 through 02014 |
| 3G3210V00237 or | 00100 through 01016 |
| 1650B2000-01 (right hand) | 02000 through 02017 |

Table 1 to Paragraph (a)

(b) Unsafe Condition

This AD defines the unsafe condition as an MLG shock absorber screw that does not

meet specifications. This condition could result in failure of the MLG shock absorber,

collapse or retraction of the MLG, and subsequent damage to the helicopter.

(c) Comments Due Date

We must receive comments by September 17, 2018.

(d) Compliance

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

(e) Required Actions

- (1) Within the following compliance times, replace each screw P/N NAS1351–5H12P installed on an MLG shock absorber with a screw P/N 1652A0001–01. Re-identify the MLG assembly using black permanent ink by marking an "R" at the end of the S/N of the MLG assembly and cover with a transparent coating. For purposes of this AD, a "landing" is counted any time the helicopter lifts off into the air and then lands again regardless of the duration of the landing and regardless of whether the engine is shut down:
- (i) For MLG assemblies with 26,800 or more landings, within 100 hours time-inservice (TIS).
- (ii) For MLG assemblies with between 22,000 and 26,799 landings, within 300 hours TIS or before the MLG assembly accumulates 27,200 landings, whichever occurs first.
- (iii) For MLG assemblies with less than 22,000 landings, within 1,200 hours TIS or before the MLG assembly accumulates 23,200 landings, whichever occurs first.
- (2) After the effective date of this AD, do not install an MLG assembly with a P/N and S/N listed in Table 1 to paragraph (a) of this AD on any helicopter unless the screw has been replaced and the MLG assembly reidentified as described in paragraph (e)(1) of this AD

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

- (1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9-ASW-FTW-AMOC-Requests@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.

(h) Additional Information

(1) Finmeccanica Bollettino Tecnico No. 139–397, dated April 7, 2016, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Matteo Ragazzi, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate

(Va) Italy; telephone +39–0331–711756; fax +39–0331–229046; or at http://www.leonardocompany.com/-/bulletins. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2016–0077, dated April 19, 2016. You may view the EASA AD on the internet at http://www.regulations.gov in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 3200 Landing Gear System.

Issued in Fort Worth, Texas, on July 9, 2018.

Scott A. Horn,

Deputy Director for Regulatory Operations, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018–15304 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0647; Product Identifier 2017-SW-083-AD]

RIN 2120-AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Bell Helicopter Textron Canada Limited (Bell) Model 429 helicopters. This proposed AD would revise the life limit for the nose landing gear (NLG) assembly. This proposed AD is prompted by revised airworthiness limitations determined by Bell. The actions of this proposed AD are intended to prevent an unsafe condition on these helicopters.

DATES: We must receive comments on this proposed AD by September 17, 2018.

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 by searching for and locating Docket No. FAA-2018-0647; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the Transport Canada AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (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 rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at http://www.bellcustomer.com/files/. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email matthew.fuller@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

Transport Canada, which is the aviation authority for Canada, has issued Canadian AD No. CF-2016-07, dated March 4, 2016, to correct an unsafe condition for Bell Model 429 helicopters with wheeled landing gear. Transport Canada advises that Bell has replaced the airworthiness limitations for the NLG main fitting to bell crank bolt part number (P/N) M084-20H125-101 and NLG main fitting P/N M084-20H011-107 with an airworthiness limitation for the next higher assembly, NLG assembly P/N 429-336-100-101. According to Transport Canada, the NLG assembly's life limit is reduced to 50,000 retirement index number (RIN) or 4,500 hours time-in-service (TIS). Transport Canada advises that failure to replace components prior to established airworthiness limitations could result in an unsafe condition.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, 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 helicopters of the same type design.

Related Service Information

We reviewed Bell Alert Service Bulletin No. 429–15–24, Revision A, dated September 23, 2015, which specifies updating the Bell 429 maintenance manual with Revision 24 to incorporate the revised airworthiness limitations for the NLG assembly, NLG main fitting to bellcrank bolt, and the NLG main fitting.

Proposed AD Requirements

This proposed AD would revise the life limit of the NLG assembly by requiring, before further flight, removing from service any NLG assembly P/N 429–336–100–101 that has reached or exceeded 4,500 hours TIS or 50,000

RIN. Thereafter, this proposed AD would require removing from service each NLG assembly P/N 429–336–100–101 before it accumulates 4,500 hours TIS or 50,000 RIN, whichever occurs first.

Differences Between This Proposed AD and the Transport Canada AD

The Transport Canada AD applies to certain serial-numbered helicopters, whereas this proposed AD would apply to all Bell Model 429 helicopters with the affected NLG assembly installed.

Costs of Compliance

We estimate that this proposed AD would affect less than 75 helicopters of U.S. Registry (as this proposed AD would not apply to Bell Model 429 helicopters with skid landing gear). At an average labor rate of \$85 per hour, replacing a NLG assembly would require 10 work-hours, and required parts would cost \$104,648, for a cost of \$105,498 per helicopter and up to \$7,912,350 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):

Bell Helicopter Textron Canada Limited: Docket No. FAA–2018–0647; Product Identifier 2017–SW–083–AD.

(a) Applicability

This AD applies to Bell Helicopter Textron Canada Limited Model 429 helicopters with a nose landing gear (NLG) assembly part number (P/N) 429–336–100–101 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as fatigue failure of an NLG assembly, which could result in subsequent damage to and loss of control of the helicopter.

(c) Comments Due Date

We must receive comments by September 17, 2018.

(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

Before further flight, remove from service any NLG assembly P/N 429–336–100–101 that has reached or exceeded 4,500 hours time-in-service (TIS) or 50,000 retirement index number (RIN). Thereafter, remove from service each NLG assembly P/N 429–336– 100–101 before accumulating 4,500 hours TIS or 50,000 RIN, whichever occurs first. For purposes of this AD, for every normal retraction or extension of the wheeled landing gear system, add one RIN.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

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

(g) Additional Information

(1) Bell Helicopter Alert Service Bulletin No. 429–15–24, Revision A, dated September 23, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at http://www.bellcustomer.com/files/. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF–2016–07, dated March 4, 2016. You may view the Transport Canada AD on the internet at http://www.regulations.gov in the AD Docket.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 3200 Nose Landing Gear.

Issued in Fort Worth, Texas, on July 9, 2018.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2018-15305 Filed 7-18-18; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2014-F-2307]

Humic Product Trade Association; Withdrawal of Food Additive Petition (Animal Use)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; withdrawal of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2290) proposing that the food additive regulations be amended to provide for the safe use of humate, fluvic acid, and humic substances as a source of iron in animal feed.

DATES: The food additive petition published on January 6, 2015 (80 FR 422), was withdrawn on April 19, 2018.

ADDRESSES: For access to the docket to read background documents or comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts; and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Carissa Doody, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6283, Carissa.doody@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In a notice of petition published in the Federal Register on January 6, 2015 (80 FR 422), FDA announced that a food additive petition (FAP 2290) had been filed by Humic Products Trade Assn., P.O. Box 963, Spring Green, WI 53588. The petition proposed to amend part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573), to provide for the safe use of humate, fluvic acid, and humic substances as a source of iron in animal feed. Humic Products Trade Assn., has now withdrawn the petition without prejudice to a future filing in accordance with 21 CFR 571.7.

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2018–15394 Filed 7–18–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1926

[Docket ID: OSHA-2015-0012]

RIN 1218-AD07

Cranes and Derricks in Construction: Railroad Roadway Work

AGENCY: Occupational Safety and Health Administration (OSHA), Labor. **ACTION:** Proposed rulemaking.

SUMMARY: The Occupational Safety and Health Administration published its final rule for cranes and derricks in construction on August 9, 2010. The final rule set out new requirements to enhance worker safety around cranes and derricks. On October 7, 2010, the Association of American Railroads ("AAR") filed a petition for review in the United States Court of Appeals for the District of Columbia challenging certain requirements affecting railroad roadway work. Subsequently OSHA and AAR reached a settlement agreement under which OSHA agreed to undertake rulemaking to propose expanding several exemptions and to issue clarifications affecting work on or along railroad tracks. These exemptions and clarifications, which would not apply to bridge work, would exempt entirely one type of railroad equipment from OSHA's crane standard; would exempt railroad equipment operators from the certification requirements in the standard; and would include several provisions relating to safety devices, work-area controls, out-of-level work, dragging loads sideways, equipment modifications, and manufacturer requirements. OSHA believes this proposal, if promulgated, would maintain safety and health protections for workers while reducing employers' compliance burdens.

DATES: Submit comments to this proposed rule, public hearing requests, and other information no later than September 17, 2018. Each submission must bear a postmark or provide other evidence of the date of submission.

ADDRESSES: Submit comments, hearing requests, and other materials, identified with this docket, Docket No. OSHA—2015–0012, using any of the following methods:

Electronically: Submit comments and attachments, as well as hearing requests and other information, electronically via the Federal e-Rulemaking Portal at http://www.regulations.gov. Follow the

online instructions for making electronic submissions.

Facsimile: Commenters may fax submissions that are no longer than 10 pages in length, including any attachments, to the OSHA Docket Office at (202) 693-1648. These submissions must include Docket No. OSHA-2015-0012 [RIN: 1218-AD07]. OSHA does not require hard copies of the faxed comments. Commenters must submit documents longer than 10 pages (e.g., supplemental attachments, comments, research studies, or journal articles) to the OSHA Docket Office, Technical Data Center, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue NW, Washington, DC 20210. These attachments must clearly identify the commenter's name, and the date, subject (Cranes and Derricks in Construction: Railroad Roadway Work), and docket number (i.e., OSHA-2015-0012) of the submission so the Agency can attach them to the appropriate submission. See also Regular mail, express delivery, hand delivery, and messenger (courier service) below.

Regular mail, express mail, hand (courier) delivery, or messenger service. Submit a copy of comments and any additional material (e.g., studies, journal articles) to the OSHA Docket Office, Docket No. OSHA-2015-0012, Technical Data Center, U.S. Department of Labor, Room N-3653, 200 Constitution Avenue NW, Washington, DC 20210; telephone: (202) 693-2350 (TDY number: (877) 889-5627). Note that security procedures may result in significant delays in receiving comments and other written materials by regular mail. Contact the OSHA Docket Office for information about security procedures concerning delivery of materials by express mail, hand delivery, or messenger (courier) service. The hours of operation for the OSHA Docket Office are 10:00 a.m. to 3:00 p.m.

Information Collection Requirements. OSHA welcomes comments on the information collection requirements contained in this rule on the same basis as for any other aspect of the rule. Interested parties may also submit comments about the information collection requirements directly to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OSHA (RIN 1218-AD07), Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503, Fax: 202-395-6881, email: OIRA submission@omb.eop.gov. See Paperwork Reduction Act section of this preamble for particular areas of interest. *Instructions*: All submissions must

include the Agency's name (OSHA), the

title of the rulemaking (Cranes and Derricks in Construction: Exemption Expansions for Railroad Roadway Work), and Docket No. OSHA-2015-0012. OSHA places submissions, comments, and other materials, including any provided personal information, in the public record of this docket without revision. Submitted materials will be available online at http://www.regulations.gov. Therefore, OSHA cautions commenters about submitting materials that contain personal information (either about themselves or others) such as Social Security numbers, birth dates, and medical data.

OSHA requests comments on all issues related to this proposed rule, including whether these revisions will have any economic, paperwork, or other regulatory impacts on the regulated community.

Docket: To read or download submissions or other materials in the public record for this docket (including material referenced in the preamble), go to http://www.regulations.gov or contact the OSHA Docket Office by telephone or the address listed above. While the Agency lists all documents for this docket in the http:// www.regulations.gov index, some information (e.g., copyrighted material) is not publicly available through the website for reading or downloading. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office at the above address. Contact the OSHA Docket Office for assistance locating submissions.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Mr. Frank Meilinger, OSHA Office of Communications, telephone: (202) 693–1999; email: Meilinger.Francis2@dol.gov.

General and Technical inquiries: Mr. Garvin Branch, Directorate of Construction, telephone: (202) 693–2020; email: Branch.Garvin@dol.gov.

Copies of this **Federal Register** document and news releases: Electronic copies of these documents are available at OSHA's web page at http://www.osha.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
- II. Background
- III. Summary and Explanation of the Proposed Rule
- IV. Preliminary Economic Analysis and Regulatory Flexibility Act Analysis
- V. Legal Considerations, Authority VI. Office of Management and Budget Review
- Under the Paperwork Reduction Act
 VII. Federalism

VIII. State-Plan States

- IX. Unfunded Mandates Reform Act of 1995 X. Consultation and Coordination With Indian Tribal Governments
- XI. Review by the Advisory Committee for Construction Safety and Health XII. Public Participation

I. Executive Summary

The Occupational Safety and Health Administration (OSHA) and the Association of American Railroads negotiated a settlement to resolve litigation following OSHA's issuance of its Cranes and Derricks in Construction standard in 2010. This rulemaking satisfies part of OSHA's obligations under that settlement. OSHA proposes to exempt entirely certain railroad "roadway maintenance machines" from the requirements of that standard, and to create limited exemptions for other equipment used by railroads for trackrelated construction activities other than bridge construction. New section § 1926.1442 would clarify that operators of the relevant equipment need not comply with the operator certification requirements in OSHA's standard. OSHA believes that these limited exemptions will maintain safety protections for workers.

OSHA has estimated the cost and cost savings for this proposed rule. At a 3 percent discount rate over 10 years, there are net annual cost savings of \$15.7 million per year, and at a discount rate of 7 percent there are net annual cost savings of \$17.0 million per year. When the Department uses a perpetual time horizon to allow for cost comparisons under E.O. 13771 (82 FR 9339, February 3, 2017), the annualized cost savings of the proposed rule is \$17.0 million with 7 percent discounting. This proposed rule is accordingly expected to be an E.O. 13771 deregulatory action. Details on OSHA's cost/cost savings estimates for this proposed rule can be found in the rule's economic analysis.

II. Background

OSHA published its final rule for cranes and derricks in construction on August 9, 2010 (29 CFR 1926 Subpart CC, 75 FR 47906). The crane standard resulted from years of work by a negotiated rulemaking committee that drew from industry best practices to draft regulatory requirements to prevent crane tipovers, electrocution from crane contact with power lines, workers being struck by the equipment or loads, crane collapse because of improper assembly, and other hazards associated with the operation of cranes in construction work. The crane standard added many new provisions, such as requirements to ensure safe ground conditions

underneath the equipment, mandatory safety devices, distance requirements from power lines, inspection procedures, workplace area controls to prevent workers from entering hazardous areas, and new operator certification requirements.

On October 7, 2010, the Association of American Railroads and a number of individual railroads (hereafter collective referred to as "AAR") filed a petition challenging the rule. That petition remains before the United States Court of Appeals for the District of Columbia Circuit (Case No. 10-1386), but after AAR provided more background and additional information about existing practices in the railroad industry, the parties reached a settlement in which OSHA agreed to issue an interpretation of its standard as it relates to ground conditions for railroads 1 and to propose the revisions to the regulatory text of the crane standard included in this proposal (see Docket ID: OSHA-2015-0012-0002). The settlement followed extensive discussions with AAR and officials from the Federal Railroad Administration and the principal labor organization representing affected employees, the Brotherhood of Maintenance of Way Employees. OSHA also reviewed the settlement with the Brotherhood of Railroad Signalmen. In deciding to enter into the settlement, OSHA acknowledged the lack of a record of significant injuries or fatalities resulting from the use of cranes or derricks for railroad track construction and maintenance and the consensus between labor and management groups that the proposed exemptions and alternatives would continue practices generally accepted as safe in the railroad industry. The settlement was narrowly tailored to address the aspects of the railroad industry that differ significantly from the more typical construction work covered by the standard.

The proposed revisions include two groups of exemptions: One for certain equipment with low-hanging attachments used to perform track work, and a second for certain requirements applicable to all railroad machines used in track construction and covered by OSHA's standard. The settlement contains draft regulatory language, which forms the basis of this proposal, but OSHA did not commit to a specific final regulatory action as part of the settlement and seeks public comment on this proposal. AAR has agreed to move to dismiss its petition within seven days of OSHA's publication of a final rule addressing these issues.

III. Summary and Explanation of the Proposed Standard

OSHA has long classified work performed to place or repair significant sections of railroad track, ties, and roadbed as construction activity subject to OSHA's construction standards in 29 CFR part 1926.2 The railroad industry relies on a number of different pieces of equipment to deliver and position the ballast rock that supports the railroad ties, the ties that support the rail, and the rail itself. Most of this equipment falls within the scope of OSHA's Cranes and Derricks Standard in subpart CC because it is "power operated equipment" and includes some form of hoisting device that allows the equipment to be used to "hoist and lower and horizontally move a suspended load" (see 29 CFR 1926.1400(a)). Railroads also use the equipment to install railway signal posts and to keep the tracks and the areas immediately alongside the track free from debris and other impediments to trains.

The railroad industry classifies this equipment collectively as "roadway maintenance machines," which are defined in Federal Railway Administration (FRA) regulations as devices "powered by any means of energy other than hand power. . . being used on or near railroad track for maintenance, repair, construction or inspection of track, bridges, roadway,3 signal, communications, or electric traction systems. Roadway maintenance machines may have road or rail wheels or may be stationary" (49 CFR 214.7). AAR provided examples of common forms of this equipment, with photos, in a memorandum to OSHA (see Docket ID: OSHA-2015-0012-0006).

A. Exemption for Flash-Butt Welding Trucks and Equipment With Similar Attachments

Flash-butt welding trucks are roadway maintenance machines with low-hanging workhead attachments. These machines are equipped with an attachment designed to suspend and move a welding workhead low and close to the rails in order to weld

precisely two sections of rail together. Other machines that would fall within this proposed exemption are similarly designed to suspend and move specific operation workheads low to the rails. This class of machines does not have any other hoisting device. AAR provided examples of these machines (see Docket ID: OSHA–2015–0012–0008).

Because these machines are not capable of raising and suspending the workhead more than a few feet above the ground or roadbed, and the weight and structure of the workhead does not appear to present any danger of equipment tipover at any point during the workhead's full range of motion, OSHA preliminarily accepts AAR's assertion that equipment in this class does not present the types of safety hazards that OSHA intended to address in its crane standard. Therefore, given that it does not appear to compromise worker safety, OSHA proposes to revise § 1926.1400(c) to expressly exempt flash-butt welding trucks and "other railroad roadway work machines equipped only with hoisting devices used to suspend and move their workhead assemblies low and close to the rails." OSHA requests comment on this proposed exemption.

B. New Section 29 CFR 1926.1442 To Address Railroad Equipment

Existing section 1926.1442, which addresses severability, is currently the last section of the crane standard. OSHA proposes to re-designate the severability provision as § 1926.1443 to enable the addition of a new § 1926.1442 dedicated to the railroad roadway maintenance machines addressed in this proposed rulemaking.

OSHA's crane standard, 1926 Subpart CC, is organized so that generalized requirements affecting cranes and derricks in construction come first in the subpart. The bulk of the standard is composed of these generalized requirements, such as those governing ground conditions; various assembly/ disassembly requirements; safety devices and operational aids; crane/ derrick operations; work area control; keeping clear of the load; and operator qualification and certification. Additional sections focus on specific types of equipment, such as tower cranes and overhead and gantry cranes, and small equipment with a rated hoisting/lifting capacity of 2,000 pounds or less. There are also railroad-specific exceptions and requirements in various sections.4

¹ See Nov. 14, 2014 letter to AAR Counsel Jill Hyman Kaplan, Esq., available at www.osha.gov.

² See, e.g., Sec'y of Labor v. Consolidated Rail Corp. (May 28, 1981), 9 OSHC Cas. (BNA) 1892, 1981 OSHD (CCH) P 25421, 1981 WL 18909; see also Memorandum for Regional Administrators, Construction vs. Maintenance, From James W. Stanley (August 11, 1994), available at www.osha.gov.

³ The "roadway" referenced in this definition does not refer to a road over which cars or trucks would travel; within the railroad industry it refers to the area encompassing the tracks, track support, and nearby items that could foul the track (see, e.g., the definition of "roadway worker" in 49 CFR 214.7).

⁴Existing railroad provisions in the crane standard include exemptions from ground

Rather than insert various railroad roadway machine exceptions throughout Subpart CC, the proposal consolidates them into a single section (§ 1926.1442) for the convenience of affected parties and to maintain the organizational integrity of Subpart CC. As proposed, aside from the § 1926.1400(c)(18) exclusion for flashbutt welding trucks and similar equipment, § 1926.1442 would contain all the new proposed provisions addressed through the settlement, all of which are provisions with which OSHA preliminarily agrees.

C. Scope of New § 1926.1442

OSHA's proposed limited exemptions for railroads in § 1926.1442 would apply to work on the construction of railroad tracks and supporting structures (the railroad ties supporting the tracks, the ballast and road bed that support the track and ties, and the poles and other structures on which railroad signal devices and signage are mounted). AAR explained that these construction activities are typically performed using equipment created specifically for railway work or specially modified for that purpose (Docket ID: OSHA-2015-0012-0007). AAR also explained that this specialized equipment is not typically used for construction of buildings, retaining walls, fences, or platforms controlled by railroads, or for other more traditional types of construction work related to railroads. Rather, those traditional construction activities are often contracted out to construction firms and typically involve standard construction equipment. OSHA is not proposing any new or special treatment for equipment used to conduct these traditional construction activities that are not related to track work. OSHA is not aware of any need for additional exceptions, and OSHA is not aware of any significant differences in the hazards of using railroad equipment for these purposes than for similar projects in other industries.

Proposed § 1926.1442 accomplishes the limitation in two ways. First, this new § 1926.1442(a) states that it only applies to equipment meeting the 49 CFR 214.7 definition of "Roadway Maintenance Machine," which includes a functional component focused on track work (machines "being used on or near railroad track for maintenance, repair, construction or inspection of track, bridges, roadway, signal,

condition and inspection requirements as set forth in §§ 1926.1400(h), 1926.1402(f), and 1926.1412(d)(1)(x) and (d)(1)(xiii); restrictions on locomotive crane movements in § 1926.1417(z); and an exception from the signal transmission requirements in 1420(b)(2).

communications, or electric traction systems''). Thus, a crane owned by a railroad would not meet the definition of a roadway maintenance machine when engaged in constructing a building or railway platform, but the same crane could later meet the definition if used to install railway track

Second, proposed § 1926.1442(a) explicitly excludes roadway maintenance machines engaged in bridge work from the limited exemptions in that section. The use of cranes and derricks on bridges exposes workers to the same hazards as in other construction work, and Subpart CC addresses those hazards without exceptions. Proposed § 1926.1442(a) makes clear that employers engaged in bridge work would still be required to comply with all of the applicable Subpart CC requirements for cranes or derricks used during that work even when using roadway maintenance machines. Worker safety remains paramount. Bridge construction work encompasses work on bridges supporting track over features such as gullies, highways, rivers, and walkways, along with work on bridges built over the track to support things such as structures, automobile roadways, and pedestrian and livestock walkways.

Subpart CC would continue to apply to all railroad construction activities, including construction using roadway maintenance machines, unless one of the proposed exceptions found at § 1926.1442(b) ⁵ applies (or one of the existing exceptions in other sections applies).

For the remainder of this document, references to the proposed exceptions for roadway maintenance machines or exempt equipment are intended to refer only to roadway maintenance machines not used for bridge work.

D. § 1926.1442(b)(1)

This proposed section would provide exemptions in accordance with Section 4(b)(1) of the OSH Act, which exempts from the Act the working conditions of certain Federal and non-Federal employees with respect to which other Federal agencies exercise statutory authority to prescribe and enforce occupational safety and health standards.

Following OSHA's promulgation of the crane standard in Subpart CC, the

FRA promulgated its own training requirements for operators of roadway maintenance machines equipped with cranes. This FRA rule included a clear statement in the preamble that after the effective date of its new rule, "FRA regulations would apply to operators of roadway maintenance machines equipped with a crane, rather than OSHA's regulation related to crane operator qualification and certification found at 29 CFR 1926.1427" (79 FR 66460, 66475 (Nov. 7, 2014)). This FRA action has the effect of prohibiting OSHA, under section 4(b)(1) of the OSH Act, from enforcing its operator certification requirements with respect to operators of roadway maintenance machines (including roadway maintenance machines used for bridge construction).

The Agency is therefore including in § 1926.1442(b)(1) an explicit exemption from proposed § 1926.1427 for these operators, to provide clear notice to employers in the railroad industry who might not otherwise be aware of the effect of the FRA's rule on OSHA's standard. Although OSHA's additional operator training requirements in § 1926.1430 were not explicitly mentioned in the FRA's rule, OSHA has included the § 1926.1430 operator training requirements in the proposed § 1926.1442(b)(1) exemption for roadway maintenance machine operators based on the FRA's statement of intent to exercise jurisdiction over all aspects of operator training.

OSHA will also consider an exemption for roadway maintenance machine operators from operator assessment requirements that it is separately considering. OSHA initiated a rulemaking on that issue following the settlement discussions and the FRA final rule; the rulemaking would revise § 1926.1427 to require employers to evaluate their operators to ensure competency to operate specific cranes (see RIN 1218-AC96 in DOL's Fall 2017 Semiannual Regulatory Agenda). Although the FRA's final rule predated that rulemaking, OSHA preliminarily reads FRA's statement about replacing "OSHA's regulation related to crane operator qualification and certification found at 29 CFR 1926.1427" as intended to preempt all OSHA requirements that would apply to the training, certification, and assessment of operators of roadway maintenance machines. Thus, if OSHA does revise § 1926.1427 to add new operator assessment requirements, OSHA could take action through this rulemaking or the other operator assessment rulemaking to clarify that the new requirement would not apply to

⁵ Proposed § 1926.1442(b) refers to the seven subparagraphs that lay out proposed exceptions. In the version of the draft regulatory text attached to the settlement, paragraph (b) incorrectly referred to six subparagraphs. With AAR's agreement, OSHA has referenced the correct number (seven) in the proposed rule.

roadway maintenance machine operators. OSHA seeks comment on this issue, and more generally on whether OSHA should include additional preamble discussion or changes to regulatory text to address issues arising from section 4(b)(1) of the OSH Act.

E. § 1926.1442(b)(2)

This provision would provide an exemption from existing Subpart CC requirements for using rail stops and rail clamps on all Subpart CC-covered equipment. Those requirements address hazards posed by locomotive cranes, which can swing loads at varying radii around the machine and force the machine to tip or move. AAR has explained, however, that rail stops are not typically used on railroad tracks and that many roadway maintenance machines are designed to move continuously over the tracks, so stops would interfere with the normal function of the equipment. Clamps are used occasionally, but manufacturers typically require their use when the clamps are needed for safety purposes. OSHA has not located any record of injuries that have resulted from the absence of stops or clamps on railroad equipment used during track construction and accordingly, because it appears that worker safety would not be compromised, proposes a partial exemption from the rail clamp or stop requirement.

The proposed § 1926.1442(b)(2)(i) and (ii) would exempt employers using roadway maintenance machines while performing OSHA regulated construction activities from the requirement for rail stops while performing construction activities and would mandate the use of rail clamps only when required by the manufacturer, in accordance with existing railroad practices. If a machine's manufacturer requires using rail clamps, then the employer would have two options: (1) Ensure that the clamps are used; or (2) operate without clamps only if a registered professional engineer (RPE) determines that the clamps are not necessary. OSHA includes the proposed RPE requirement to address concerns raised by AAR that, because railroad equipment often represents only a small percentage of a crane manufacturer's market and is often specially modified for railroad use, the manufacturers are often not responsive to requests for approval of modifications or exceptions from general requirements developed for nonrailroad use. An option for RPE approval thus could provide an alternative measure of safety while accommodating that aspect of railroad

roadway operations. RPE approval is required, or allowed as an alternative, in a number of provisions of OSHA's crane standard (see, *e.g.*, §§ 1926.1404(j) and (m)(1)(i); 1417(b)(3); 1434(a)(2)(i); 1435(f)(3)(ii)).

OSHA also requests comment on whether the language of the proposed exception is clear and welcomes suggestions for clarifying it. For example, would it be clearer if OSHA replaced the "except/unless" construct with a more lengthy provision like the following: "(i) The requirement for rail clamps in § 1926.1415(a)(6) does not apply when clamps are not required by the manufacturer. When a manufacturer requires rail clamps, the employer is not required to use them if a registered professional engineer determines that rail clamps are unnecessary"?

F. § 1926.1442(b)(2)(iii)

This section would clarify that the requirements of § 1926.1424(a)(2) do not apply to certain employers. These requirements cover work-area controls to prevent employee injuries from the movement of the crane, such as the rotation of the crane structure as it moves a load laterally. Most of the methods of work area control involve cordoning off a work area to ensure that employees do not enter hazardous areas during crane operations. In the railroad industry, however, equipment is often continuously moving down a railroad track, so physically fixed controls would be difficult to implement. The FRA also requires employers to file a written safety program that addresses work-area safety for FRA approval (see 49 CFR 214.307(b)). Thus, although existing § 1926.1424(a)(2) allows employers to use signage in combination with special training where it is infeasible to erect a cordon, it is not clear how that alternative would comport with existing FRA requirements or what safety benefit it would add. The FRA already has a mechanism by which it can ensure that employers put in place protections to prevent the types of hazards that OSHA intended to prevent through its workarea control requirements. OSHA believes that, with respect to employers required to submit on-track safety programs with the FRA, the FRA's program preempts the work-area-control requirements in OSHA's crane standard based on the preemption provisions of 4(b)(1) of the OSH Act. Thus, proposed § 1926.1442(b)(2)(iii) states that § 1926.1424(a)(2) does not apply to any railroad employers that are required to implement an FRA-approved on-track safety program. OSHA notes that although the proposed regulatory text

only explicitly addresses such employers when they actually implement such a plan, OSHA expects that it would be preempted from enforcing its 1926.1424(a)(2) requirements even if the employer failed to file or implement a program with the FRA because the FRA has exercised its jurisdiction with respect to those employers. OSHA is considering adding language in the final rule to clarify that such employers would also be exempt.

OSHA's is also proposing to exempt from its § 1926.1424(a)(2) requirements employers who are not required to implement an FRA-approved on-track safety program but who are nevertheless implementing such a protective program, because the FRA program would provide safety protections for employees. Employers who are not required to implement a FRA-approved program and are not implementing one would be required to comply with OSHA's § 19126.1424(a)(2) requirements.

G. § 1926.1442(b)(3)

This proposed section would exempt roadway maintenance machines from existing restrictions on out-of-level work. These restrictions, including the requirements to comply with manufacturer out-of-level procedures in § 1926.1402(b), the inspection requirements in § 1926.1412(d)(l)(xi), and the requirement that machines have out-of-level indicators in § 1926.1415(a)(l), address the risk of equipment tipover and loss of control of the load.

OSHA has preliminarily determined that the prohibition on out-of-level work is not practical for railroad roadway track work. In addition to thousands of miles of straight and level track, much curved track is banked and many other miles of track are inclined, as are the structures or road bed supporting the track. In 2010, OSHA responded to the unique railroad conditions with an exception to the out-of-level work prohibition for railroad equipment, but limited the exception to include only equipment traveling on the tracks (see § 1926.1402(f)). Following the rulemaking, AAR explained that many roadway maintenance machines, like a swing loader crane, often travel next to the track (as opposed to on it) but frequently must work out-of-level because the ballast and road bed are sloped. These cranes typically lift loads, which are well below the crane capacity, only a few feet off the ground and thus do not present the same type of risks as more traditional uses of cranes in construction. Both the relevant labor organizations and FRA

representatives acknowledged that outof-level operation is longstanding and necessary practice in the industry. AAR explained that industry practices already account for load-chart adjustments and other standard practices to address out-of-level work, and OSHA is proposing alternative measures to ensure that the work can be performed safely.

OSHA accordingly proposes in § 1926.1442(b)(3)(i) and (ii) to allow outof-level operation when two conditions are met. First, either the manufacturer must approve or modify the equipment to allow out-of-level work, or a registered professional engineer qualified with respect to the particular equipment must approve the out-oflevel work for the equipment. Second, the employer must abide by the limitations and other requirements specified by the manufacturer or the engineer, or comply with a load chart modified by a qualified person for the approved out-of-level work. While OSHA expects the qualified person generally to follow the requirements established by the manufacturer or registered professional engineer, given the many unique areas of railroad work, in some cases a manufacturer or engineer might not have accounted for a particular activity that would require an additional adjustment to the load chart. OSHA included the option of allowing a qualified person to make additional adjustments to the load chart so that the employer would not need to stop work and locate an RPE every time an additional adjustment to the load chart is necessary. OSHA requests comment on whether OSHA should provide additional guidance about the types of adjustments that a qualified person may make and the extent to which the manufacturer or RPE must spell out its approval for out-of-level work.

OSHA has drafted this exemption to include a parenthetical naming the particular sections as follows: "The restrictions on out-of-level work (including the requirements in §§ 1926.1402(b), 1926.1412(d)(l)(xi), and 1926.1415(a)(l)), and the requirements for crane-level indicators and inspections of those indicators do not apply when [lists circumstances]." But OSHA is considering relocating all or part of the parenthetical to follow 'those indicators'' given that § 1926.1415(a)(1) addresses requirements for crane-level indicators and inspections of those indicators, but does not otherwise address restrictions on out-of-level work. Under this option, the sentence would read "The restrictions on out-of-level work, and

the requirements for crane-level indicators and inspections of those indicators (including the requirements in §§ 1926.1402(b), 1926.1412(d)(l)(xi), and 1926.1415(a)(l)), would not apply when" OSHA requests comment on which approach would be clearer.

In addition to the exemption described above, this proposed section includes a "grandfathering" provision to exempt roadway maintenance machines from all out-of-level prohibitions if the machines were purchased before OSHA's crane standard took effect on November 8, 2010. AAR explained that older machines represent the vast majority of equipment currently used in the railroad industry and has expressed concern about the cost of obtaining manufacturer or RPE approval for outof-level work for that number of pieces of equipment. Based on the lack of reported safety incidents involving these machines, OSHA has preliminarily determined to include an exemption for them. As a result of this exemption for older equipment, railroad employers would be able to focus their resources on obtaining manufacturer approval as part of the process of purchasing new equipment and focusing RPE expertise on equipment that has not already been as time-tested.

OSHA is also proposing a "grandfathering" provision for the requirements in § 1926.1415(a)(1) that all covered equipment have a built-in level or a level available on the equipment and that employers inspect such level indicator to confirm that it is functioning properly (§ 1926. 1412(d)(1)(xiv)). AAR informed OSHA that most roadway maintenance machines were manufactured prior to OSHA's promulgation of the crane standard in 2010, and are not currently equipped with level indicators. AAR objected to the cost of retrofitting them with such leveling equipment if such equipment would be allowed to operate out-of-level because they were grandfathered out of the out-of-level requirements. OSHA included the requirement for a level to ensure that the equipment operator would be able to comply with the restrictions on out-oflevel work, so OSHA preliminarily agrees that there would be little purpose to requiring a level on the equipment if the out-of-level restrictions do not apply. Therefore, in addition to the exception for out-of-level work, OSHA is also proposing a "grandfather" provision that would relieve railroad employers of the requirement to include or inspect crane-level indicators on roadway maintenance machines purchased before the effective date of OSHA's construction crane standard

(November 8, 2010). OSHA expects that equipment purchased after that date will already be equipped with a level to comply with OSHA's crane standard.

OSHA requests comments on its proposed grandfathering exemptions from out-of-level prohibitions and associated level indicator and indicator inspection requirements. It also requests comments on whether used equipment originally purchased before November 8, 2010, but resold at a later date should be entitled to these grandfathering exceptions. OSHA also requests comment on whether the "grandfathering" provisions should be conditioned on other factors, such as a certain number of years of safe use or evidence of regular maintenance on the machine. The Agency further requests any data on these subjects that could better inform its decision making.

H. § 1926.1442(b)(4)

Dragging a load sideways. The proposed § 1926.1442(b)(4) exemption provides relief from the prohibition in § 1926.1417(q) against using cranes or derricks to drag a load sideways. AAR informed OSHA that an existing practice during many track construction projects for roadway maintenance machines is to drag rail or ties sideways. AAR explained that the practice of dragging long pieces of rail sideways off of the ties or to position them on top of the ties is routine and critical to the process, does not have a ready alternative, does not involve lifts more than a few feet off of the ground, and the movement of the load is predictable because the procedure is repeated over and over with the same materials. OSHA has not located any record of injuries resulting from the longstanding practice of using railroad equipment during track construction and accordingly proposes an exemption from the new prohibition on dragging a load sideways.

I. § 1926.1442(b)(5)

Boom-hoist limiting device. This proposed section would clarify existing § 1926.1416(d)(1), which requires equipment manufactured after December 16, 1969, to have a boomhoist limiting device. Traditionally, boom hoists wind wire rope around a revolving drum. They continue to wind until stopped by the operator, a limiting device, or by damaging the machine. The process is somewhat analogous to a fisherman winding line on a rod and reel: If too much winding occurs, the lure is pulled into the rod tip; more winding bends and breaks the rod or detaches the lure. The limiting device prevents similar results on boom hoist

equipped cranes and derricks by automatically stopping the winding. On hydraulic cylinder/piston equipped booms, the § 1926.1416(d)(1) requirement for a limiting device is redundant because the stroke or piston travel is an inherent limit in each cylinder/piston. OSHA proposes § 1926.1442(b)(5) to clarify that roadway maintenance machines using a hydraulic piston for raising and lowering the boom do not need a separate boom-hoist limiting device. The addition of this provision should not adversely affect worker safety.

J. § 1926.1442(b)(6)

Manufacturer guidance for modifications covered by § 1926.1434. The proposed rule would modify the application of § 1926.1434, which requires employers to obtain and follow equipment manufacturer's guidance for equipment modifications except in certain circumstances, for the railroad roadway context. Many roadway maintenance machines are modified for railroad use. AAR stated that some manufacturers of these machines no longer exist and others are often reluctant to approve modifications for a variety of reasons, including liability concerns arising from their lack of expertise in railroad operations. AAR argued that employers in the railroad industry are best suited to oversee the safety of railroad equipment modification based on their long history of safe operation with modified equipment. OSHA agrees that given the unique nature of the railroad industry and the equipment used for track work, it would be appropriate to simplify how a railroad employer may use modified equipment without involving the manufacturer, but continuing to include safety assurances. Modifications covered by this exception would include: Alterations to the physical structure of the equipment and modifications to the use of the equipment, such as adding metal wheels for operation on railroad tracks, increasing charted capacity by shortening and strengthening the lattice boom, or increasing reach by lengthening the boom and reducing charted capacity.

According to proposed § 1926.1442(b)(6), an employer may use modified railroad roadway maintenance equipment regardless of manufacturer guidance when three conditions are met. First, an RPE qualified with respect to the equipment must approve the procedure, modifications, addition, or repair; specify the equipment configurations described in the approval; and modify applicable

procedures, load charts, manuals, instructions, plates, tags, and decals. Second, the employer must operate the equipment within the specifications and limitations set by the engineer. Third, taking into account the modifications and procedures, the equipment's safety factor must remain at or above 1.7 for the structural integrity of the boom, or 1.25 for stability, unless the original safety factors were lower. The "safety factor" of the equipment is a common term used to assess the strength and stability of cranes, and OSHA derived these safety factors based on its engineering judgment. OSHA believes that these safety factors can be readily determined by an engineer based on documentation and analyses. The language of this exception was based on the existing provision in § 1926.1431(a)(2) allowing employers to modify equipment when a manufacturer refuses to review the request. In some cases, equipment manufacturers specify safety factors less than 1.7 and 1.25. In those cases, the employer could rely on the manufacturer's specifications. But if the original safety factor of the equipment is not available or was originally set at or higher than 1.7 or 1.25, the proposed exception would allow equipment modifications resulting in a safety factor no lower than 1.7 for the structural boom and 1.25 for stability, subject to the other provisions of the exception (RPE approval). OSHA requests comments on this proposed exception, including the safety factors and the proposal to allow compliance with lower manufacturer-specified values. OSHA also requests comment on whether the structure of proposed paragraph (b)(6)(i) would be improved by moving the last clause of subparagraph (A), "and specifies the equipment configurations to which that approval applies;" to a separate subparagraph (B) to make it clearer that this is a separate requirement (proposed subparagraph (B) would be redesignated as subparagraph (C)).

K. § 1926.1442(b)(7)

Other manufacturer guidance. This proposed exception would apply to several other sections of Subpart CC that require employers to follow manufacturer's guidance, instructions, procedures, prohibitions, limitations, or specifications. The restrictions are found in §§ 1926.1404(j), (m), or (q); 1926.1417(a), (r), (u), or (aa); 1926.1433(d)(l)(i); and in 1926.1441. The proposed exemptions in § 1926.1442(b)(7) would allow employers to use roadway maintenance machines without regard for the manufacturer's listed restrictions if the

following conditions are met: (1) An RPE familiar with the equipment provides a written determination of the appropriate limitations for equipment use; and (2) the employer does not exceed those limitations. Like the exemption in proposed § 1926.1442(b)(6) above, this proposed exemption responds to practices in the railroad industry of modifying equipment from manager specifications for the unique needs of railway maintenance. This exemption is intended to preserve existing use practices in the railroad industry while relying on the expertise of an RPE familiar with the equipment to ensure the safety of the equipment for departures from manufacturer guidance. The exemption also provides employers a means to operate safely in cases where obtaining manufacturer's approval is impossible, such as when the manufacturer no longer exists.

OSHA requests comments on all of the proposed exemptions and their explanations provided in this document.

L. Requirement for RPE Determinations To Be in Writing

The agency notes that there is some inconsistency between different proposed exemptions as to whether required determinations by RPEs or others must be in writing. For example, proposed § 1926.1442(b)(2)(i) conditions part of the exemption on an RPE determination that rail clamps are not necessary, but does not explicitly require that determination to be in writing. Likewise, proposed § 1926.1442(b)(3)(i) requires RPE approval of out-of-level work but does not specify that the approval be in writing. However, proposed § 1926.1442(b)(7)(i) would require written approval from an RPE for modifications not approved by a manufacturer. OSHA requests comment on whether it should require all of the determinations and approvals to be in writing to ensure accurate communication and facilitate enforcement.

IV. Preliminary Economic Analysis and Regulatory Flexibility Act Analysis

Executive Orders 12866 and 13563 require OSHA estimate the benefits, costs, and net benefits of regulations. Executive Orders 12866 and 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1532(a)) also require OSHA to estimate the costs, assess the benefits, and analyze the impacts of certain rules that the Agency promulgates. Executive Order 13563

emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

The cost savings for employers for this proposed rule are the difference between the 2010 rule and the residual costs, which is a savings of \$15.7 million per year at a discount rate of 3 percent. This proposal is not economically significant within the meaning of Executive Order 12866, nor is it a major rule under the Unfunded Mandates Reform Act or Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.). In addition, this rule complies with Executive Order 13563.

When it issued the final crane standard in 2010, OSHA prepared a final economic analysis (FEA) to ensure compliance with the OSH Act and Executive Order 12866 (58 FR 51735) (Sept. 30, 1993). OSHA also published a Final Regulatory Flexibility Analysis as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). On September 26, 2014, the Agency included additional economic analysis when it published a final rule extending the employer duty to ensure operator competency and the deadline for all crane operators to become certified (79 FR 57785.) Because OSHA did not have sufficient data at the time, OSHA did not include in either rulemaking a complete assessment of the economic impact on the railroad industry.

This preliminary economic analysis (PEA) not only addresses the economic impact of the proposed revisions to the crane standard, but also completes the analysis of the impact of the entire crane standard on the railroad industry. This analysis relies primarily on the same methodology applied to other industries in the 2010 economic analysis of the crane standard. In conducting that analysis, the Agency relies mainly on the best available economic data provided by AAR to the Agency as part of its settlement agreement. The Agency provided a list of questions to AAR, which then surveyed Class I freight railroad members and returned the results, along with other general responsive information, to OSHA. Those responses (referenced as AAR 2015) as

well as some estimates from the economic analysis supporting the September 26, 2014, operator certification deadline extension final rule form the basis of this PEA.

The proposed exemptions would relieve the railroad industry of several cost burdens related to the crane standard. OSHA estimates that the 2010 rule would have cost the railroad industry \$24.2 million annually. The residual costs the industry would still face after factoring in the exemptions in this proposed rule would be \$8.5 million per year. Finally, the cost savings for employers for this proposed rule are the difference between the 2010 rule and the residual costs, which is a savings of \$15.7 million per year. These estimates are at a discount rate of 3 percent. At a discount rate of 7 percent the economic analysis of the 2010 rule would have costs of \$25.6 million annually. The residual costs the industry would still face with the regulatory changes in this proposed rule would be \$8.6 million per year. Finally, the cost savings for employers for this proposed rule are the difference between the 2010 rule and the residual costs, which is a savings of \$17.0 million per year. When the Department uses a perpetual time horizon to allow for cost comparisons under E.O. 13771, the annualized cost-savings of this proposed rule is the same: \$17.0 million with 7 percent discounting.

a. Scope of the Exemption

The railroad industry is typically divided into three "classes" of railroads according to a revenue-based classification scheme developed by the Surface Transportation Board (STB).7 Class I railroads are the largest railroads with the greatest amount of revenue and primarily comprise seven large freight railroads and the Amtrak passenger train service. They operate the vast majority of track across the country. Class II and III railroads are smaller freight railroad companies, various commuter lines, and other specialty lines that operate much smaller sections of track or operate on track owned by the larger railroads.

OSHA has imperfect information about the three classes of railroads. The AAR survey only covered the Class I freight railroads. AAR was also able to provide some additional information it obtained from Amtrak, but due to the patchy nature of national statistics for the railroad industry, OSHA has not been able to obtain corresponding data for Class II and Class III railroads.

Therefore, for this NPRM, the Agency has used indirect estimates to scale up partial data to create estimates for the industry as a whole. The U.S. Department of Transportation states that Class I freight railroads operated 94,400 miles (68%) of the 139,400 total miles in the U.S. system.8 Amtrak stated that it maintains 852 miles of track (Amtrak, 2017). In combination with Class I freight track, the total Class I track estimate is therefore 95,252 (94,400 miles operated by Class I freight + 852 miles operated by Amtrak) out of the total U.S. track of 139,400. AAR also stated that its members operate 6,935 machines that might fall within the scope of OSHA's crane standard (AAR, 2015), and Amtrak stated that it operates 303 machines that might fall within that standard (Amtrak, 2017). Assuming that non Class-I railroads use machines in the same way as Class I, OSHA is able to estimate the total number of potentially covered equipment by scaling up the total number of Class I machines by the ratio of total track to Class I track, or 1.46 (139,400/(94,400 + 852)).9 With the total number of Class I machines at 7,238 (6,935 freight + 303 Amtrak), the final estimate of all railroad industry machines is 10,593 $(7,238 \times 1.46)$. To the extent that Class I railroads perform track work for other segments of the railroad industry, this markup will be an overestimate. The Agency solicits comment and any further data on this issue.

Based on information provided by FRA staff from its Office of Safety Analysis, OSHA estimates that there are a total of 775 railroads (OSHA discussion with FRA staff, September 9, 2014). AAR reported that in 2012 the total number of freight railroads, including the 7 Class I freight railroads, was 574 (AAR, 2014). The remainder of the railroads are passenger and commuter railroads, intra-plant railroads (that do not operate on the national freight system), freight car manufacturers, freight car repair facilities or companies that provide specialized rail services, and switching and terminal railroads. The Agency

⁶At a discount rate of 7 percent the cost savings are \$17.0 million per year. Estimates in this economic analysis are derived from OSHA's economic analysis of the 2010 rule, other public sources, and a survey performed by AAR of its members and provided to OSHA under the settlement agreement for use in this analysis (AAR, 2015). Due to rounding as shown in the text versus the underlying exact spreadsheet calculations, some text calculations may vary from the exact presented totals. All dollar amounts in the text are brought forward to 2017 dollars.

⁷ See 49 CFR 1201, General Instructions 1–1. Class I railroads are those with annual carrier operating revenues of more than \$250 million, Class II railroads are those with operating revenues between \$20 million and \$250 million, and Class III railroads have annual revenues less than \$20 million.

⁸ "The United States had almost 140,000 railroad route-miles in 2014, including about 94,400 miles owned and operated by the seven Class I freight railroads. Amtrak, local, and regional railroads operated the remaining 45,000 miles." (DOT/BTS, 2016, p. 16 (internal citation omitted)).

⁹ From this point forward, this PEA refers to the ratio of total track to Class I track (1.46) as "the standard markup".

assumes 2012 data continue to approximate industry conditions today.

To estimate the cost savings from the NPRM exemptions, the number of machines must be broken out into subcategories. First there is a small group of Class I machines that would fit into the proposed full exemption for flash-butt welding trucks and similar equipment under proposed 1400(c)(18). AAR reported that its members had 22 machines that would fall within the proposed exemption, (AAR, 2015),10 while Amtrak indicated that none of its equipment would (Amtrak, 2017). Using the same ratio to account for this exempt equipment in Class II and III railroads, OSHA estimates that there is a total of 32 pieces of such exempt equipment across the entire railroad industry (1.46 \times 22). Thus, OSHA estimates that 7,216 (7,238-22) Class I machines, and an industry total of 10,561 (10,593 – 32) machines, would fall under at least some provisions of the crane rule and would not, even upon finalization of this proposed rule, be completely exempt from the crane standard.

Second, OSHA estimates that there are 186 Class I machines exclusively engaged in bridge work, and a further 269 Class I machines, including 2 Amtrak machines, used to do both track and bridge work, all of which would be covered to some extent by the OSHA construction crane standard (the proposed exemptions do not apply to bridgework). Because some costs will need to be taken into account if any bridge work at all is performed by a machine, the Agency took the conservative approach of lumping together those doing some bridge work with those doing bridge work exclusively. 11 OSHA only estimates cost savings for machines used exclusively for non-bridge work. Thus, the number of Class I machines that will still need to comply with all of the provisions in the crane standard (other than the operator training and certification provisions) is 455 (186 + 269), with an industry total of 666 machines (455 \times 1.46) outside the proposed limited exceptions and covered by the crane standard.

b. Non-Operator Base Costs of 2010 Crane Standard for Railroads

Railroads are subject to all requirements of the 2010 crane standard (unless previously exempted in the 2010 rule or, upon finalization, specifically exempted through this rulemaking). An economic analysis of the costs imposed by that standard on the industry was not presented in the 2010 final rule and is, therefore, presented here. Table B-9 of the final rule (75 FR 48104) shows that railroads are in the "Own but Do Not Rent" sector of the industry profile. The Agency estimates the costs of the 2010 rule by using the costs for the "Own but Do Not Rent" sector as a proxy for railroad costs, scaling these aggregate costs by the size of the railroad industry as presented above. The Agency recognizes this proxy may be imperfect and solicits comment and additional information regarding these estimates.

Costs other than certification will be incurred by railroad employers using equipment covered by OSHA's crane standard. Most 2010 rule provisions other than operator certification and training are not operator specific, so the Agency estimates the cost of the existing requirements by identifying the percrane non-operator cost of the 2010 final rule and applying that cost (inflated to 2017 dollars) to the number of affected machines in the Railroad sector. Then OSHA identifies the costs that would be avoided if the proposed exemptions are adopted.

The "Own but Do Not Rent" sector in Table B–9 (75 FR 48104) has total operator certification costs of \$30,606,452 and overall total costs of \$62,651,984, leaving \$32,045,531 in non-certification costs (\$62,651,984 - \$30,606,452). The "Own but Do Not Rent" sector was listed as having 50,807 cranes and other covered equipment (Table B-11, 75 FR 48107). Thus, excluding operator certification costs, OSHA's 2010 cost estimates for the "Own but Do Not Rent" sector amounted to \$631 per machine (\$32,045,531/50,807). Using the 1.12 GDP deflator factor this cost brought forward to 2017 dollars is \$707 (BEA, 2017).

Based on this per-machine cost of the 2010 rule and the estimate of 10,593 total pieces of railroad equipment covered by the 2010 rule, the total

annual base non-operator cost of the 2010 rule to the entire railroad industry would be \$7,486,362 (10,593 \times \$706.75; 2017 dollars). The proposed exception for flash-butt welding trucks and similar equipment would remove 32 machines and lower the cost in 2017 dollars to \$7,463,607 (10,561 \times \$706.75), which is a savings of \$22,755.

These are the base non-operator costs only. There are two pieces of equipment specific to cranes on rails that would have a special impact on railroads absent the proposed exemptions: Rail clamps and rail stops. These were not included in the base costs and are addressed next.

c. Rail Clamps and Rail Stops

Rail clamps are one type of equipment that would no longer be required under the proposed exemption. AAR told OSHA that the railroad industry does not typically use rail clamps for most operations and indicated that 5,663 additional rail clamps beyond what the Class I railroad industry currently has in stock would need to be purchased to comply with the existing rule (AAR, 2015). Further communication from AAR stated that Amtrak would need 157 additional clamps (Amtrak, 2017). These rail claims would impose new up-front, maintenance, and replacement costs on the industry.

OSHA estimates a total cost for rail clamps of \$51,104,943, plus an additional \$4,897,557 for maintenance. OSHA derives these costs first by applying the standard markup of 1.46 to estimate non-Class I railroad use clamps as $8,517 (1.46 \times (5,663 + 157))$. OSHA then estimates the up-front cost for each unit. AAR's survey reported as follows: "The majority of the railroads indicated that the unit cost for a rail clamp is \$5,000–\$6,000. However, one of the railroads contacted a manufacturer and obtained a unit cost of \$10,000." (AAR, 2015 p. 5). OSHA's costs are estimated to reflect the average costs for most firms, so the Agency selects the higherend of the typical cost of \$6,000 from the AAR survey. Therefore, the total cost for rail clamps would be $$51,104,943 (8,517 \times $6,000).$ Annualized over 10 years at a discount rate of 3%, the annualized cost is \$5,991,058. Annual maintenance costs per clamp are estimated at \$575 13 for a total annual maintenance cost of $\$4,897,557 (8,517 \times \$575).$

OSHA also estimates annual replacement costs of \$3,741,650 associated with the clamp requirement for the railroad industry. From the (AAR

¹⁰ For the purposes of this analysis, OSHA has treated all flash-butt welding trucks and similar equipment as covered by the standard absent the proposed exemption.

¹¹The AAR survey asked what percentage of time these dual use machines and operators were doing track work and the response was 90–95%. Hence for certain costs this allocation of assuming all their work is on bridges will underestimate cost savings.

¹² In the 2010 rulemaking, OSHA did not include any additional costs for operator training, other than certification exam preparation, because operator training was already required under the previous standard. Thus, this analysis relies exclusively on operator certification costs as the costs avoided by the exemption for railroads from OSHA's operator training and certification requirements.

 $^{^{13}}$ This is the midpoint of the range in the AAR survey of \$450 to \$700 (\$575 = (\$450 + \$700)/2).

2015) survey, the number of replacement clamps needed over 10 years for Class I freight is 4,223. OSHA did not receive an estimate for the number of replacement clamps that Amtrak or the Class II and III railroads would use, so the Agency has developed an estimate for additional replacement clamps based on the ratio of Class I freight railroad track to all other track. The resulting markup factor for purely Class I freight track as compared to the entire U.S. railroad industry track is 1.48 (139,400 miles of total U.S. track/ 94,400 miles of Class I freight track). Applying this freight markup to the total number of replacement clamps produces an estimate of 6,236 for the entire industry $(4,223 \times 1.48)$. If 10% of these clamps are replaced each year, then with the unit cost equal to the purchase price of \$6,000, annual replacement costs will total \$3,741,650 $(6,236 \times 10\% \times \$6,000)$. ¹⁴ Summed together, the annual cost savings for rail clamps for the railroad industry are \$14,630,265 (\$5,991,058 initial cost + \$4,897,557 maintenance + \$3,741,650 replacement clamps).

Rail stops are the second type of equipment that would no longer be required under the proposed exemption. For rail stops, OSHA estimates total upfront costs of \$5,110,494 and maintenance costs of \$511,049, AAR indicated that 11,326 additional rail stops beyond what the Class I freight railroads currently have in stock would need to be purchased (AAR, 2015). Amtrak indicated it would need an additional 314 stops (Amtrak, 2017). The standard (track-based) markup derived earlier in this PEA and applied to the sum of Class I rail stops and Amtrak rail stops produces an estimated 17,035 additional rail stops for the entire industry $(1.46 \times (11,326 + 314))$. The unit cost of a rail stop is \$300 each (AAR, 2015); therefore, the total cost of rail stops is \$5,110,494 (17,035 \times \$300). Annualized over 10 years at a discount rate of 3%, the annual cost is \$599,106. Annual maintenance costs per stop are \$30 (AAR, 2015); therefore, total maintenance cost is \$511,049 (17,035 \times

OSHA also estimates annual replacement costs of \$462,324 associated with the rail stop requirement for the railroad industry. The number of replacement stops for the Class I freight railroads needed over 10 years is 10,436 (AAR, 2015). OSHA did not receive information regarding the

number of replacement stops required for Amtrak or the Class II and III railroads. OSHA again focuses on the ratio of all U.S. railroad track to Class I freight railroad track, which is 1.48. The number of replacement stops needed for the whole industry is 15,410 $(1.48 \times 10,436)$. If 10% of the replacement stops will be introduced each year then 1,541 replacement railroad stops will be required each year $(15,410 \times .10)$. The estimate of the annual unit cost for these replacement stops is the unit cost for buying a new rail stop of \$300.15 Hence the total annual cost for replacement rail stops is \$462,324 (1,541 × \$300). Summed together, annual cost savings of railroad stops are \$1,572,479 (\$599,106 + \$511,049 + \$462,324).

Adding the total costs savings of both railroad stops and clamps in 2016 dollars gives \$16,202,744 (\$14,630,265 + \$1,572,479). In year 2017 dollars, the cost savings for both railroad stops and clamps is \$16,704,394.

The Agency has adjusted these costsavings estimates to account for the costs that the railroad industry will incur for rail clamps and stops related to bridgework because the proposed exemption does not cover rail clamps and stops used in bridge construction activity. To adjust for these costs, the Agency proxies rail clamp use on bridges by AAR's survey responses for such use by machines. Based on the estimates identified earlier, there are a total of 666 machines engaged in bridgework out of 10,561 total machines (assuming that flash-butt machines as not engaged in any bridge work). Hence the estimate of the share of rail clamps that will be exempted is 94% (10,561-666)/10,561). The total cost for bridge work for clamps and stops is $$1,053,284 ($16,704,394 \times (1-.94)).$ That cost will remain for the industry even if the proposed exemptions are ultimately finalized, but the remaining rail clamp and rail stop costs would be avoided. The cost savings due to the proposed exemption for clamps/stops is $$15,651,110 ($16,704,394 \times .94)$ in 2017dollars.

d. Work Area Controls

OSHA estimates no economic impact from the proposed exemption from compliance with the crane standard's work-area controls requirements. FRA already requires a number of work area controls to prevent injury to those working on or around railroad equipment and OSHA believes that even if the proposed exemption from workarea controls is not finalized, the railroads could comply with OSHA's requirements without incurring significant new costs. Therefore, OSHA is neither identifying a new cost for this requirement nor treating the proposed exemption as resulting in any cost saving.

e. Out-of-Level Work

The 2010 crane rule economic analysis did not estimate any cost increase due to this provision. Thus, there would be no resulting savings from this exemption.

f. Dragging a Load Sideways

The 2010 crane rule economic analysis estimated no increased cost due to this provision, and OSHA has likewise included no cost saving from the exemption from it. It is possible that the exemption does result in significant cost savings: AAR indicated that railroad equipment regularly needs to drag long portions of rail sideways during the process of installing or replacing the rail, ties, or underlying road bed. Therefore AAR asserted that the prohibition on dragging a load sideways would force railroad employers to substantially change current practices for track installation and replacement. If such changes were feasible, they would likely incur significant cost. However, because OSHA did not previously estimate any increased costs for this provision, OSHA has not included any cost saving as part of this rulemaking.

g. Boom-Hoist Limiting Device

The 2010 crane rule economic analysis estimated that such boom hoist limiting devices would generally already be in place, where needed. Hence OSHA did not include any new costs for this requirement in 2010, so there would be no resulting savings from this exemption.

h. Manufacturer Guidance for Modifications Covered by § 1926.1434

The 2010 crane rule economic analysis estimated that there would be no new costs due to this provision because it was similar enough to the previous Subpart N crane standard. Hence this exemption would produce no cost savings.

i. Operator Certification and Assessment

Because the FRA specifically preempted OSHA's operator training and certification requirements when it issued its own operator training rules for railroads, the costs of this standard

¹⁴ If the total pool of working clamps is kept constant, as we assume, then the maintenance costs for the replacement clamps are already accounted for in the annual maintenance costs for the original pool.

¹⁵ As in the preceding footnote, maintenance costs for these replacement stops will already be accounted for in the maintenance costs for the original pool under the assumption of a constant total pool.

for operator training and certification do not apply to railroads and thus the proposed rule would not result in any cost savings. As discussed in the preamble of this proposed rule, OSHA is also considering a separate rulemaking that would specify additional operator assessment responsibilities for each employer. OSHA expects that FRA's training rule would also preclude the OSHA's assessment requirements, if promulgated, from impacting railroad employers. At this juncture, OSHA does not anticipate any cost to railroad employers as a result of OSHA's requirements for employer assessment of operators, whether or not OSHA modifies the assessment requirements.

j. Total Cost and Savings From Proposal

Finally, adding together the rail clamp/stop costs and the base nonoperator costs, the total cost of the 2010 rule is \$24,190,756 (\$16,704,394 + 7,486,362). Factoring in the proposed exemptions, the total costs that will still be incurred by the industry are \$8,516,891 (\$1,053,284 clamps and stops + \$7,463,607 base non-operator costs). Cost savings of the proposal are \$15,673,865 (\$24,190,756 - \$8,516,891). These calculations are at a discount rate of 3%, using 2017 dollars. At a discount rate of 7%, the costs would be as follows: Total costs of \$25,648,173, total ongoing costs of \$8,608,788, and cost savings of \$17,039,385.

k. Economic Impacts

This section investigates the economic impacts of this proposal, whether the proposed rule is economically feasible for the industry as a whole, and whether the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

OSHA applies two threshold tests to look at economic feasibility for firms overall, regardless of size: Whether the rule's costs as a percentage of revenues for a sector as a whole are below 1 percent, and whether those costs as a percentage of profits are below 10 percent. For small entities there are also two threshold tests: Whether the costs for small entities are 1 percentage of their revenues or below, and whether those costs are 5 percent or less of the small entities' profits. None of these threshold tests are hard ceilings or determinative; they are guidelines the Agency uses to examine whether there are any potential economic feasibility issues that require additional study. As for the overall totals estimated above, the Agency must use indirect estimates since no public firm-by-firm information exists.

The Agency relies on SBA size standards to classify a company as "small." The SBA size standard for a small entity in the railroad industry is employment of 1,500 or less (SBA, 2016). The seven Class I freight railroads employ a total of 162,819 employees, or an average of 23,260 employees per firm (162,819/7). The Agency estimates that all 7 freight railroads will be above the 1,500-employee SBA size standard. Amtrak has more than 20,000 employees, and will also be well above the small entity threshold (https:// www.amtrak.com/about-amtrak/amtrakfacts/amtrak-national-facts.html). While there is likely to be a skew among non-Class I railroads and some of these freight railroads may actually exceed the threshold for small businesses, for the purposes of this analysis the Agency treats all 767 non-Class I firms (775 railroads - 8 Class I railroads) as below the SBA size standard of 1,500 employees.

According to AAR, the Class I freight railroads in 2012 had revenue ¹⁶ of \$67.6 billion out of the total of \$71.6 billion for the entire freight industry, so the share of Class I freight revenues is 94 percent (67.6/71.6), while \$4 billion (71.6 – 67.6) are the revenues for small freight railroads (AAR, 2014).

OSHA applied AAR's report of 2012 operating income (profits) for Class I to estimate the average profits of the non-Class I railroads. Class I freight railroads' net income was \$11.9 billion (AAR, 2014), and assuming that the Class I net income share was the same as its operating revenue share, OSHA derives a total freight industry net income of \$12.6 billion (\$11.9/.94) in 2012, and hence small freight railroad total net income of \$704 million (\$12.6 \$11.9) in 2012. OSHA did not receive income estimates regarding non-freight railroads, so applying the standard freight-only markup to those totals to account for passenger rail, OSHA estimates \$18.6 billion (\$12.6 \times 1.48) and \$1.0 billion (\$704 \times 1.48), respectively, for total railroad (including passenger rail) and small railroad net income (including passenger rail). Using the GDP deflator to convert these amounts to 2017 dollars results in \$19.9 billion and \$1.1 billion, respectively.

Finally, OSHA allocates costs to the small railroads. The share of employment, rather than revenue, was judged to be the better proxy to estimate the costs of small railroads. From the information provided earlier, Class I freight employment is 90% of total freight railroad employment and the total railroad industry freight costs are \$24.1 million, so total small railroad industry costs are \$2.4 million (\$24.1 million \times (1 - .90)). The revenues, profits, and costs are set out in Table 1.

TABLE 1 TOTAL AND SMALL RAILROAD INDUSTRY ESTIMATED FINANCIAL STATISTICS

| Description | 2017 Dollars |
|---|----------------|
| Revenue: | |
| Total Revenue | \$113 billion. |
| Small Entity Revenue | 6.3 billion. |
| Profit: | |
| Total Profit | 19.9 billion. |
| Small Entity Profit | 1.1 billion. |
| Cost: | |
| Total Cost (existing) | 24.2 million. |
| Total Cost (with proposed exemption) | 8.5 million. |
| Small Entity Cost (existing) | 2.5 million. |
| Small Entity Cost (with proposed exemption) | 155,068. |

¹⁶ These are freight revenues rather than total revenue. (AAR 2014) only reports freight, rather than total, revenue for non-Class I railroads. In 2013, Class I freight revenue was 70.5 billion while

total revenue was 72.9 billion, or 97% (70.5/72.9). Using only freight revenue will give a slight underestimate of total revenues, and a slight overestimate of the final ratio wanted: (costs/revenue).

The ratio of the proposed rule's costs to revenue for total railroads is .02% (\$24.2m/\$113 billion) and for small railroads is .04% (\$2.5m/\$6.3 billion). The ratio of the proposed rule's costs to profits for total railroads is .12% (\$24.2m/\$19.9 billion) and for small railroads it is .22% (\$2.5m/\$1.1 billion). Both easily pass OSHA's standard threshold impacts tests of costs being below 1% of revenue and 10% of profits (5% of profits for small entities.) The proposed exemptions would drastically lower those costs, so the thresholds would be even easier to meet. These estimates are scaling several Class I numbers so the results are sensitive to whether these (scaled) numbers are representative of the rest of the industry. The Agency requests comment and further information on these issues.

1. Overhead Cost Adjustment

The Agency notes that it did not include an overhead labor cost in the PEA for this rule. It is important to note that there is not one broadly accepted overhead rate and that the use of overhead to estimate the marginal costs of labor raises a number of issues that should be addressed before applying overhead costs to analyze the costs of any specific regulation. There are several approaches to examine the cost elements that fit the definition of overhead and there are a range of overhead estimates currently used within the federal government. For example, the Environmental Protection Agency has used 17 percent, 17 and government contractors have been reported to use an average of 77 percent. 18 19 Some overhead costs, such as advertising and marketing, vary with output rather than with labor costs. Other overhead costs vary with the number of new employees. Rent or payroll processing costs may change little with the addition of 1 employee in a 500-employee firm, but those costs may change substantially with the addition of 100 employees. If an employer is able to rearrange current employees' duties to implement a rule, then the marginal share of overhead

costs such as rent, insurance, and major office equipment (e.g., computers, printers, copiers) would be very difficult to measure with accuracy (e.g., computer use costs associated with 2 hours for rule familiarization by an existing employee).

If OSHA had included an overhead rate when estimating the marginal cost of labor, without further analyzing an appropriate quantitative adjustment, and had adopted an overhead rate of 17 percent on base wages, as was done in a sensitivity analysis in the FEA in support of OSHA's 2016 final rule on Occupational Exposure to Respirable Crystalline Silica, such rate would have only affected the non-operator certification costs estimated from the 2010 rule. Because labor costs were only part of those costs, including this overhead adjustment would have increased the average cost per machine from \$631 to \$684, a 9 percent increase. Using this larger per machine cost in the rest of the analysis would increase the final cost savings of this proposal from \$15.674 million to \$15.676 million at a discount rate of 3 percent, an increase of .01 percent. It would also have increased cost savings from \$17.039 million to \$17.041 million at a discount rate of 7 percent, an increase of .01 percent.

m. Economic and Technological Feasibility

All requirements of the proposed rule have now been in place since the promulgation of the crane standard in 2010, and the only feasibility issues for the railroad industry raised with OSHA were addressed through its settlement with AAR. For example, AAR raised concerns that it would not be feasible for railroads to avoid dragging rails sideways because this activity is an essential component of railroad construction. OSHA is now proposing to exempt railroads from this prohibition in the 2010 crane standard on dragging loads sideways. The Agency does not have sufficient information to estimate the costs to the railroad industry of this prohibition. It also does not have enough data to estimate the cost savings that could result from the proposed exemption but they could be significant. OSHA requests information to help it better estimate the cost-saving implications of this proposed exemption. Beyond the issues raised by AAR and addressed in the settlement, the Agency is not aware of any special infeasibility issues that are unique to the railroad industry and the 2010 technological feasibility analysis is equally applicable to the railroad industry.

OSHA found that the 2010 final crane standard is feasible for all affected industries because the "[c]osts of 0.2 percent of revenues and 4% of profits will not threaten the existence of the construction industry, affected general industry sectors, or the use of cranes in affected industry sectors," and no change in the competitive structure of those industries was expected (75 FR 48112). The above analysis shows that the cost of the 2010 rule on railroads is 0.02 percent of revenues and 0.13 percent of profits, and the proposed rule, which would exempt railroads from many of the requirements of the 2010 rule would be still less costly. This supports OSHA's finding that the 2010 final rule is economically feasible for all affected industries (including railroads) and a finding that the OSHA proposal is also economically feasible. The Agency preliminarily concludes that the proposed rule is both economically and technologically feasible for the railroad industry.

n. Certification of No Significant Impact on a Substantial Number of Small Entities

In determining that the 2010 final rule would not have a significant impact on a substantial number of small entities, OSHA found that in no case would a small entity have to increase prices more than 0.18 percent or, if costs could not be passed on, absorb costs comprising more than 5.0 percent of profits (75 FR 47913, 48115). As discussed above, as applied to small railroads, the 2010 rule would be just 0.04 percent of revenues and 0.24 percent of costs, which supports OSHA's 2010 determination as applied to railroads. Because the proposed rule would exempt railroads from several of the requirements of the 2010 rule, the proposed rule would reduce the cost impact on small entities. Thus, the Agency certifies that the proposed rule will have not have a significant impact on a substantial number of small entities.

References

AAR, 2014. Association of American Railroads, "Class I Railroad Statistics," July 15, 2014. Available at: https:// www.aar.org/StatisticsAndPublications/ Documents/AAR-Stats.pdf. (Accessed 12/6/2017.)

AAR, 2015. Association of American Railroads. "AAR's Response to OSHA Economic Questions," memo from AAR to OSHA, June 22, 2015.

Amtrak, 2017. Amtrak. "Amtrak Response to OSHA Economic Questions," via email from AAR (August 8, 2017, and November 2, 2017).

¹⁷ U.S. Environmental Protection Agency, "Wage Rates for Economic Analyses of the Toxics Release Inventory Program," June 10, 2002.

¹⁸ Grant Thornton LLP, 2015 Government Contractor Survey. (https:// www.grantthornton.com/~/media/content-pagefiles/public-sector/pdfs/surveys/2015/Gov-Contractor-Survey.ashx.).

¹⁹ For a further example of overhead cost estimates, please see the Employee Benefits Security Administration's guidance at https:// www.dol.gov/sites/default/files/ebsa/laws-andregulations/rules-and-regulations/technicalappendices/labor-cost-inputs-used-in-ebsa-opr-riaand-pra-burden-calculations-august-2016.pdf.

- BEA, 2017. Bureau of Economic Analysis,
 Table 1.1.9. Implicit Price Deflators for
 Gross Domestic Product. Available at
 http://www.bea.gov/iTable/
 iTable.cfm?ReqID=9&step=
 1#reqid=9&step=3&isuri=1&904=
 1995&903=13&906=a&905=2016&910=
 x&911=1. (Accessed March 23, 2017.)
- USDOT/BTS 2016. U.S. Department of Transportation, Bureau of Transportation Statistics, "Transportation Statistics Annual Report 2016," Washington, DC: 2016. Available at https://www.bts.gov/ sites/bts.dot.gov/files/docs/TSAR_ 2016.pdf.
- OSHA, 2016. Occupational Safety and Health Administration, Operator Certification Notice of Proposed Rulemaking, Summary and Economic Analysis.
- SBA, 2016. Small Business Administration, "Table of Small Business Size Standards Matched to North American Industry Classification System Codes," February 2016.

V. Legal Considerations

The purpose of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.) is "to assure so far as possible every working man and woman in the nation safe and healthful working conditions and to preserve our human resources." 29 U.S.C. 651(b). To achieve this goal, Congress authorized the Secretary of Labor to promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b), 655(b). A safety or health standard "requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment or places of employment." 29 U.S.C. 652(8). A standard is reasonably necessary or appropriate within the meaning of Section 652(8) when a significant risk of material harm exists in the workplace and the standard would substantially reduce or eliminate that workplace risk. See Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607 (1980). In the 2010 crane rulemaking, OSHA made such a determination with respect to the use of all cranes and derricks in construction, including cranes used in the railroad industry (75 FR 47913, 47920–21). This proposed rule includes a number of exemptions and does not impose any new requirements on employers. Therefore it does not require an additional significant-risk finding (see Edison Elec. Inst. v. OSHA, 849 F.2d 611, 620 (D.C. Cir. 1988)).

In addition to materially reducing a significant risk, a safety standard must be technologically feasible. See *UAW* v. *OSHA*, 37 F.3d 665, 668 (D.C. Cir. 1994). A standard is technologically feasible when the protective measures it requires already exist, when available

technology can bring the protective measures into existence, or when that technology is reasonably likely to develop (see Am. Textile Mfrs. Inst. v. OSHA, 452 U.S. 490, 513 (1981); Am. Iron & Steel Inst. v. OSHA, 939 F.2d 975, 980 (D.C. Cir. 1991)). In the 2010 Final Economic Analysis for the crane standard, OSHA found the standard to be technologically feasible (75 FR 48079). Also, this proposed rule is technologically feasible because it would not require employers to implement any additional protective measures. Instead, it would offer employers new compliance alternatives and exemptions.

VI. Office of Management and Budget Review Under the Paperwork Reduction Act

A. Overview

The purposes of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., include enhancing the quality and utility of information the Federal government requires and minimizing the paperwork and reporting burden on affected entities. The PRA requires certain actions before an agency can adopt or revise a collection of information (also referred to as a "paperwork" requirement), including publishing a summary of the collection of information and a brief description of the need for, and proposed use of, the information. The PRA defines "collection of information" as "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format" (44 U.S.C. 3502(3)(A)). Under the PRA, a Federal agency may not conduct or sponsor a collection of information unless it is approved by the Office of Management and Budget (OMB) and displays a currently valid OMB control number, and the public is not required to respond to a collection of information unless it displays a currently valid OMB control number (44 U.S.C. 3507). Also, notwithstanding any other provisions of law, no person shall be subject to penalty for failing to comply with a collection of information if the collection of information does not display a currently valid OMB control number (44 U.S.C. 3512).

B. Solicitation of Comments

The "Cranes and Derricks in Construction: Railroad Roadway Work" proposal would establish new information-collection requirements. The proposal would also modify a number of information-collection requirements in the existing Cranes and Derricks in Construction Standard (29 CFR part 1926, subpart CC) Information Collection (IC) approved by OMB.

Some of these revisions, if adopted, would result in changes to the existing burden-hour and/or cost estimates associated with the currently OMB-approved information-collection requirements contained in the Cranes and Derricks in Construction Standard Information Collection. The proposed rule would also revise existing standard provisions that are not information-collection requirements. Those revisions are not addressed in this preamble section.

Concurrent with publication of this proposed rule, OSHA prepared and submitted a revised Cranes and Derricks in Construction Standard (29 CFR part 1926, subpart CC) Information Collection Request (ICR) reflecting the NPRM's new information collectionrequirements to OMB for review under control number 1218-0261. When and if the final rule is published, OSHA will submit a revised ICR for the final Cranes and Derricks in Construction Standard that will include railroad roadway work to OMB for approval. Pursuant to the PRA, the public may comment directly to OMB on the information-collection (paperwork) requirements during a 30day period following the submission of the document to OMB. This comment period is in addition to the opportunity for the public to provide comments directly to the agency.

The Agency and OMB solicit comments on the Cranes and Derricks Standard information-collection requirements as they would be established or revised by this rule. In particular, comments are sought that:

- Evaluate whether the proposed information-collection requirements are necessary for the proper performance of the Agency's functions, including whether the information will have practical utility:
- Evaluate the accuracy of OSHA's estimate of the time and cost burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

A copy of the ICR for this proposal with applicable supporting documentation, including a description of the likely respondents, estimated frequency of response, and estimated total burden, may be obtained free of charge from the RegInfo.gov website at: http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201710-1218-003 (this link will only become active on the day following publication of this document).

C. Proposed Revisions to the Information Collection Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(1), OSHA is providing the following summary information about the information-collection requirements identified in the proposal.

- 1. *Title:* Cranes and Derricks in Construction (29 CFR part 1926 subpart CC)
- 2. Description of the ICR. The proposal creates new information-collection requirements associated with the existing "Cranes and Derricks in Construction Standard" Information Collection. These information-collection requirements are discussed below and in more specific detail in Section III: Summary and Explanation of the Proposed Amendments to Subpart CC.

Sections 1926.1442(b)(2)(i) and (b)(2)(iii)—Rail Clamps and Work-Area Controls Exemptions

Section 1926.1442(b)(2)(i) exempts the railroad equipment from the requirement in § 1926.1415(a)(6) for rail clamps when the manufacturer does not require them. When the manufacturer does require the clamps, the proposal allows the employer to seek an exemption by obtaining an RPE's determination that rail clamps are not necessary.

Section 1926.1442(b)(2)(iii) provides that the work-area controls specified by § 1926.1424(a)(2) do not apply when employers have implemented an ontrack safety program that addresses work-area safety for the equipment, and the FRA approved the on-track safety program in accordance with 49 CFR 214.307(b). The FRA already has a mechanism by which it can ensure that employers put in place sufficient protections to prevent the types of hazards that OSHA intended to prevent through its work-area control requirements. OSHA expects that all covered railroad equipment will comply with the FRA requirements and therefore be exempt from OSHA's workarea requirements.

Sections 1926.1442(b)(3)(i) and (ii)— Out-of-Level Work Restriction Exemptions

OSHA's crane standard generally prohibits out-of-level operation of cranes unless approved by the manufacturer. When the manufacturer has not already authorized out-of-level work, proposed § 1926.1442(b)(3) would allow out-of-level operation for all railroad equipment purchased before November 8, 2010, and for all other equipment under two conditions that would contain information collection requirements in some scenarios: (i) The manufacturer must approve or modify the equipment to allow out-of-level work, or an RPE qualified with respect to the particular equipment must approve the out-of-level work for the equipment; and (ii) the employer must abide by the limitations and other requirements specified by the manufacturer or the engineer, or by a load chart modified by a qualified person for the approved out-of-level work. Given the many unique areas of railroad work, in some cases a manufacturer or engineer might not have accounted for a particular activity that would require an additional adjustment to the load chart. OSHA included the option of allowing a qualified person to make additional adjustments to the load chart so that the employer would not need to stop work and locate an RPE every time an additional adjustment is necessary.

Section 1926.1442(b)(6)(i)(A) and (b)(6)(i)(B)—Manufacturer Guidance for Modifications Covered by § 1926.1434 Exemptions

Current section 1926.1434 requires employers to obtain and follow equipment manufacturer's guidance for equipment modifications except in certain circumstances. OSHA is proposing an exception that would simplify how a railroad employer may use modified equipment without involving the manufacturer but continuing to include safety assurances. Under proposed § 1926.1442(b)(6), an employer would be able to use modified railroad roadway maintenance equipment regardless of manufacturer guidance when several conditions are met. Specifically, under proposed § 1926.1442(b)(6)(i)(A) and § 1926.1442(b)(6)(i)(B), an RPE qualified with respect to the equipment must approve the procedure, modifications, addition, or repair; specify the equipment configurations described in the approval; and modify applicable procedures, load charts, manuals, instructions, plates, tags, and decals.

Section 1926.1442(b)(7)—Other Manufacturer Guidance Exemption

The proposed exemption in § 1926.1442(b)(7) would apply to several other sections of Subpart CC that require employers to follow manufacturer's guidance, instructions, procedures, prohibitions, limitations, or specifications. Those restrictions are found in §§ 1926.1404(j), (m), or (q); 1926.1417(a), (r), (u), or (aa); 1926.1433(d)(l)(i); and in 1926.1441. Under the proposed exemption, employers would be allowed to use roadway maintenance machines without regard for the manufacturer's listed restrictions if certain conditions are met. A number of these conditions contain information collection requirements. Proposed § 1926.1442(b)(7)(1) provides that an RPE familiar with the equipment must provide a written determination of the appropriate limitations for equipment use. Like the exemption in proposed § 1926.1442(b)(6) above, this exemption is intended to preserve existing use practices in the railroad industry while relying on the expertise of an RPE familiar with the equipment to ensure the safety of the equipment for departures from manufacturer guidance. The exemption also provides employers a means to operate safely in cases where obtaining manufacturer's approval is impossible, such as when the manufacturer no longer exists.

- 3. Number of respondents: 210,626 (including 775 railroad establishments).
 - 4. Frequency of responses: Various.5. Number of responses: 3,045,098.
 - 6. Average time per response: Various.
- 7. Estimated total burden hours: 436,701.
- 8. Estimated cost (capital-operation and maintenance): \$2,622.994.

D. Submitting Comments

In addition to submitting comments directly to the Agency, members of the public who wish to comment on the Agency's information-collection requirements in this proposal may send written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the DOL-OSHA (RIN-1218-AD07), Office of Management and Budget, Room 10235, Washington, DC 20503. You may also submit comments to OMB by email at: OIRA submission@omb.eop.gov. Please reference control number 1218-0261 in order to help ensure proper consideration. The Agency encourages commenters also to submit their comments related to the Agency's clarification of the information collection requirements to the rulemaking docket (Docket Number

OSHA-2015-0012), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this Federal Register document titled **DATES** and **ADDRESSES**.

A copy of the ICR for this proposal, with applicable supporting documentation: Including a description of the likely respondents, estimated frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* website at: http://www.reginfo.gov/public/do/ PRAViewICR?ref nbr=201710-1218-003 (this link will only become active on the day following publication of this document). Copies of these documents may also be obtained by contacting Mr. Vernon Preston, Directorate of Construction, OSHA, Room N-3427, U.S. Department of Labor, 200 Constitution Avenue NW, Washington DC 20210; telephone: (202) 693–2020; email: Preston.Vernon@dol.gov.

VII. Federalism

OSHA reviewed this proposed rule in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, August 10, 1999), which requires that Federal agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when clear constitutional authority exists and the problem is national in scope. Generally, Executive Order 13132 allows preemption of State law only with the expressed consent of Congress. Agencies must limit any such preemption to the extent possible.

As discussed in more detail in the following section addressing State Plan States, under Section 18 of the OSH Act, Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as "State Plan States." (29 U.S.C. 667). Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

This proposed rule complies with Executive Order 13132. In States without OSHA-approved State Plans, any standard developed from this proposed rule would limit State policy options in the same manner as every standard promulgated by OSHA. In States with OSHA-approved State Plans, this rulemaking would not significantly limit State policy options.

VIII. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 28 States and U.S. Territories with their own OSHA-approved occupational safety and health plans (State-Plan States) must amend their standards to reflect the new standard or amendment, or show OSHA why such action is unnecessary (e.g., because an existing State standard covering this area is already "at least as effective" as the new Federal standard or amendment. (29 CFR 1953.5(a)). The State standard must be at least as effective as the final Federal rule and the State must complete the standard within six months after the publication date of the final Federal rule. When OSHA promulgates a new standard or amendment that does not impose additional or more stringent requirements than the existing standard, State-Plan States are not required to amend their standards. The provisions in this proposal are exemptions from existing OSHA requirements and will reduce compliance burdens on employers, and as such OSHA does not view any of the proposed provisions as more stringent than the existing standard. Therefore, States and Territories with approved State Plans may adopt comparable amendments to their standards but are not required to do so. OSHA seeks comment on this assessment of its proposal.

The 28 States and territories with OSHA-approved State Plans are: Alaska, Arizona, California, Connecticut, Hawaii, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, New Jersey, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Connecticut, Illinois, New Jersey, New York, Maine, and the Virgin Islands have OSHA-approved State Plans that apply to State and local government employees only.

IX. Unfunded Mandates Reform Act of

OSHA reviewed this proposed rule in accordance with the Unfunded Mandates Reform Act of 1995 (UMRA; 2 U.S.C. 1501 et seq.) and Executive Order 12875 (56 FR 58093). As discussed in section IV ("Preliminary Economic Analysis and Regulatory Flexibility Act Certification") of this proposed rule, the Agency determined that this proposed rule does not add

new costs because the proposed changes are exemptions. However, because OSHA did not identify the cost to the railroad industry of the Cranes and Derricks in Construction standard. OSHA is identifying that cost now as part of this rulemaking. As OSHA explained in 2010, the total costs of the crane standard exceeded the threshold of \$100 million per year and required additional analysis under the UMRA, which OSHA performed in 2010 (see 75 FR 48130). The \$8.5 million in residual costs attributed to the railroad industry does not significantly impact the Agency's previous analysis, and the PEA for this rulemaking includes an additional analysis of the economic impact of the crane standard on the

railroad industry.

As noted under section VIII ("State Plans") of this proposed rule, the Agency's standards do not impose any duties on State and local governments except in States that elect voluntarily to adopt a State Plan approved by the Agency. OSHA is not aware of any tribal governments that operate railroads using equipment that would be subject to this rulemaking, and the proposed changes create exceptions to the rule, not new duties. Consequently, this proposed rule does not meet the definition of a "Federal intergovernmental mandate" (see Section 421(5) of the UMRA (2 U.S.C. 658(5)). Therefore, for the purposes of the UMRA, the Agency certifies that this proposed rule does not mandate that State, local, or tribal governments adopt new, unfunded regulatory obligations, or increase expenditures by the private sector of more than \$100 million in any vear.

X. Consultation and Coordination With **Indian Tribal Governments**

OSHA reviewed this proposed rule in accordance with Executive Order 13175 (65 FR 67249 (Nov. 9, 2000)) and determined that it does not have "tribal implications" as defined in that order. The final rule, if promulgated as proposed, would not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes. or on the distribution of power and responsibilities between the Federal government and Indian tribes.

XI. Review by the Advisory Committee for Construction Safety and Health

OSHA must consult with the ACCSH whenever the Agency proposes a rulemaking that involves the occupational safety and health of construction employees (29 CFR 1911.10, 1912.3). Accordingly, before

the meeting date below, OSHA gave the ACCSH members a copy of the proposed revisions in this rulemaking as well as a brief summary and explanation of them. On December 1, 2016, ACCSH unanimously recommended that OSHA publish the proposal (see https://www.osha.gov/doc/accsh/meeting minutes/accsh_20161201.pdf).

XII. Public Participation

A. Submission of Comments and Access to the Docket

OSHA invites comments on the proposed revisions described, and the specific issues raised, in this proposed rule. These comments should include supporting information and data. OSHA will carefully review and evaluate these comments, information, and data, as well as any other information in the rulemaking record, to determine how to proceed.

When submitting comments, parties must follow the procedures specified in the previous sections titled **DATES** and ADDRESSES. The comments must provide the name of the commenter and docket number. The comments also should identify clearly the provision of the proposal each comment is addressing, the position taken with respect to the proposed provision or issue, and the basis for that position. Comments, along with supporting data and references, submitted on or before the end of the specified comment period will become part of the proceedings record, and will be available for public inspection and copying at http:// www.regulations.gov.

B. Requests for an Informal Public Hearing

In accordance with section 6(b)(3) of the OSH Act and 29 CFR 1911.11, members of the public may request an informal public hearing by following the instructions under the section of this **Federal Register** document titled **ADDRESSES**. Hearing requests must include the name and address of the party requesting the hearing, and submitted (e.g., postmarked, transmitted, sent) on or before September 17, 2018. All submissions must bear a postmark or provide other evidence of the submission date.

List of Subjects in 29 CFR Part 1926

Construction industry, Occupational safety and health, Railroad safety, Safety.

Authority and Signature

Loren Sweatt, Deputy Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, authorized the preparation of this document pursuant to Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 29 CFR part 1911, and Secretary's Order 1–2012 (77 FR 3912).

Signed at Washington, DC, on July 12, 2018.

Loren Sweatt,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

Proposed Amendments to Standards

For the reasons stated in the preamble above, OSHA proposes to amend 29 CFR part 1926 to read as follows:

PART 1926—SAFETY AND HEALTH REGULATIONS FOR CONSTRUCTION

Subpart CC—Cranes and Derricks in Construction

■ 1. The authority citation for Subpart CC of 29 CFR part 1926 continues to read as follows:

Authority: 40 U.S.C. 3701 *et seq.*; 29 U.S.C. 653, 655, 657; and Secretary of Labor's Orders 5–2007 (72 FR 31159) or 1–2012 (77 FR 3912), as applicable; and 29 CFR part 1911

■ 2. Amend § 1926.1400 by adding paragraph (c)(18) to read as follows:

§ 1926.1400 Scope.

* * * * * * *

(18) Flash-butt welding trucks or other roadway maintenance machines which are not equipped with any hoisting device other than that used to suspend and move a welding device or workhead assembly. For purposes of this exclusion, the terms flash-butt welding truck and roadway maintenance machine refer to railroad equipment that meets the definition of "Roadway Maintenance Machine" in 49 CFR 214.7 and is used only for railroad track work.

- 3. Redesignate § 1926.1442 as new § 1926.1443.
- 4. Add a new § 1926.1442 to read as follows:

§ 1926.1442 Railroad roadway maintenance machines.

- (a) For bridge construction work, employers using equipment covered by this Subpart CC of this part that meets the definition of "Roadway Maintenance Machine," as defined in 49 CFR 214.7, must comply with all of the requirements in this Subpart CC of this part.
- (b) For construction work other than bridge construction, employers using equipment covered by Subpart CC of this part that meets the definition of

- "Roadway Maintenance Machine" must comply with the requirements in Subpart CC of this part, except as provided in paragraphs (b)(1) through (7) of this section:
- (1) Operator certification and training. The requirements in §§ 1926 .1427 (Operator qualification and certification) and 1926.1430 (Training) do not apply.
- (2) Rail clamps, rail stops, and workarea controls. (i) The requirement for rail clamps in § 1926.1415(a)(6) does not apply; except § 1926.1415(a)(6) applies when a manufacturer requires rail clamps, unless a registered professional engineer determines that rail clamps are not necessary;
- (ii) The requirement for rail stops in § 1926.1415(a)(6) does not apply; and
- (iii) The work-area controls specified by § 1926.1424(a)(2) do not apply when employers have implemented an ontrack safety program that addresses work-area safety for the equipment and the Federal Railroad Administration approved the on-track safety program in accordance with 49 CFR 214.307(b).
- (3) Out-of-level work. The restrictions on out-of-level work (including the requirements in §§ 1926.1402(b), 1926.1412(d)(l)(xi), and 1926.1415(a)(l)), and the requirements for crane-level indicators and inspections of those indicators, do not apply when the employer uses equipment purchased before November 8, 2010, or when:
- (i) The manufacturer approves or modifies the equipment for out-of-level operation, or a registered professional engineer who is a qualified person with respect to the equipment involved approves such out-of-level work; and
- (ii) The employer uses the equipment within limitations specified by the manufacturer or the registered professional engineer, or a qualified person modifies the load chart for such approved out-of-level work and the employer uses the equipment in accordance with that load chart.
- (4) Dragging a load sideways. The prohibition in § 1926.1417(q) on dragging a load sideways does not apply.
- (5) Boom-hoist limiting device. The requirement in § 1926.1416(d)(1) for a boom-hoist limiting device does not apply to Roadway Maintenance Machines when the cranes use hydraulic cylinders to raise the booms.
- (6) Manufacturer guidance for modifications covered by § 1926.1434. The requirements to follow the manufacturer's guidance set forth in § 1926.1434 do not apply when employers meet all of the following conditions:

- (i) A registered professional engineer who is a qualified person with respect to the equipment:
- (A) Approves the procedure, modification, addition, or repair, and specifies the equipment configurations to which that approval applies; and
- (B) Modifies load charts, procedures, instruction manuals, and instruction plates, tags, and decals, as appropriate.

(ii) The employer uses the equipment in accordance with all of the engineer's specifications and modifications.

- (iii) The original safety factor of the equipment is not reduced below 1.7 for the structural boom, and 1.25 for stability, unless the original safety factor is lower.
- (7) Other manufacturer guidance. The requirements to follow the manufacturer's guidance, instructions, procedures, prohibitions, limitations, or specifications, set forth in §§ 1926.1404(j), (m), or (q); 1926.1417(a), (r), (u), or (aa); 1926.1433(d)(l)(i); or 1926.1441 do not apply when:
- (i) A registered professional engineer familiar with the type of equipment involved determines the appropriate limitations on the equipment in writing; and
- (ii) The employer does not exceed those limitations.

[FR Doc. 2018–15285 Filed 7–18–18; 8:45 am]

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2018-0619] RIN 1625-AA00

Safety Zone; Lower Mississippi River, Mile Markers 94 to 95 Above Head of Passes, New Orleans, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

summary: The Coast Guard proposes to establish a temporary safety zone for certain navigable waters of the Lower Mississippi River. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters near New Orleans, LA, during a fireworks display on October 6, 2018. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Sector New Orleans or a designated representative.

We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before August 20, 2018.

ADDRESSES: You may submit comments identified by docket number USCG—2018–0619 using the Federal eRulemaking Portal at http://www.regulations.gov. See the "Public Participation and Request for Comments" portion of the

SUPPLEMENTARY INFORMATION section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Lieutenant Commander Benjamin Morgan, Sector New Orleans, U.S. Coast Guard; telephone 504–365–2281, email Benjamin.P.Morgan@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector New
Orleans
DHS Department of Homeland Security

FR Federal Register MM Mile marker

NPRM Notice of proposed rulemaking § Section U.S.C. United States Code

II. Background, Purpose, and Legal Basis

On May 9, 2018, Zito Company, LLC notified the Coast Guard that it would be conducting a fireworks display from 9 p.m. through 10 p.m. on October 6, 2018. The fireworks are to be launched from a barge on the Lower Mississippi River at approximate mile marker (MM) 94.5, above Head of Passes, off Algiers Point, New Orleans, LA. Hazards from firework displays include discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Sector New Orleans (COTP) has determined that potential hazards associated with the fireworks display would be a safety concern for anyone within a one-mile stretch of the river.

The purpose of this rulemaking is to ensure the safety of persons, vessels, and the marine environment on the navigable waters within a one-mile stretch around the fireworks barge before, during, and after the scheduled fireworks display. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary safety zone from 9 p.m. through 10 p.m. on October 6, 2018. The

safety zone would cover all navigable waters of the Lower Mississippi River between MM 94 and MM 95, above Head of Passes. The duration of the zone is intended to ensure the safety of persons, vessels, and the marine environment on these navigable waters before, during, and after the scheduled fireworks display.

No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans. Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF-FM Channel 16 or 67. Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative. The COTP or a designated representative would inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size and short duration of the safety zone, which would impact a one-mile stretch of the Lower Mississippi River for one hour on one evening. In addition, vessel traffic seeking to transit the area may seek permission from the COTP or his designated representative to do so.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the temporary safety zone may be small entities, for the reasons stated in section IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

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.

Under section 213(a) of the Small **Business Regulatory Enforcement** Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **for further information CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this proposed rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the FOR FURTHER INFORMATION **CONTACT** section.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone lasting one hour that would prohibit entry on one-mile stretch of the Lower Mississippi River. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under ADDRESSES. We seek any comments or information that may lead to the discovery of a significant

environmental impact from this proposed rule.

G. 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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at http://www.regulations.gov. If your material cannot be submitted using http://www.regulations.gov, contact the person in the FOR FURTHER INFORMATION CONTACT section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to http://www.regulations.gov and will include any personal information you have provided. For more about privacy and the docket, visit http://www.regulations.gov/privacyNotice.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at http://www.regulations.gov and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0619 to read as follows:

§ 165.T08-0619 Safety Zone; Lower Mississippi River, Mile Markers 94 to 95, New Orleans, LA.

- (a) Location. The following area is a safety zone: All navigable waters of the Lower Mississippi River between mile marker (MM) 94 and MM 95 above Head of Passes, New Orleans, LA.
- (b) Effective period. This rule is effective from 9 p.m. through 10 p.m. on October 6, 2018.
- (c) Regulations. (1) In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless specifically authorized by the Captain of the Port Sector New Orleans (COTP) or designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector New Orleans.
- (2) Vessels requiring entry into this safety zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM Channel 16 or 67.
- (3) Persons and vessels permitted to enter this safety zone must transit at their slowest safe speed and comply with all lawful directions issued by the COTP or the designated representative.
- (d) Information broadcasts. The COTP or a designated representative will inform the public of the enforcement times and date for this safety zone through Broadcast Notices to Mariners (BNMs), Local Notices to Mariners (LNMs), and/or Marine Safety Information Broadcasts (MSIBs) as appropriate.

Dated: July 12, 2018.

Kristi M. Luttrell,

Captain, U.S. Coast Guard, Captain of the Port Sector New Orleans.

[FR Doc. 2018–15439 Filed 7–18–18; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF THE INTERIOR

National Park Service

36 CFR Part 13

[NPS-AKRO-25874; PPAKAKROZ5, PPMPRLE1Y.L00000]

RIN 1024-AE38

Alaska; Hunting and Trapping in National Preserves—Extension of Public Comment Period

AGENCY: National Park Service, Interior. **ACTION:** Proposed rule; extension of public comment period.

SUMMARY: The National Park Service is extending the public comment period for the proposed rule to amend its regulations for sport hunting and trapping in National Preserves in Alaska. Extending the comment period for 45 days will allow more time for the public to review the proposal and submit comments.

DATES: The comment period for the proposed rule published on May 22, 2018 (83 FR 23621), is extended. Comments must be received by 11:59 p.m. EST on September 6, 2018.

ADDRESSES: You may submit comments, identified by Regulation Identifier Number (RIN) 1024—AE38, by either of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail or hand deliver to: National Park Service, Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501.
- Instructions: Comments will not be accepted by fax, email, or in any way other than those specified above. All submissions received must include the words "National Park Service" or "NPS" and must include the docket number or RIN (1024–AE38) for this rulemaking. Comments received will be posted without change to http://www.regulations.gov, including any personal information provided.
- *Docket:* For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and enter "1024–AE38" in the search box.

FOR FURTHER INFORMATION CONTACT:

Herbert C. Frost, Regional Director, Alaska Regional Office, 240 West 5th Ave., Anchorage, AK 99501. Phone (907) 644–3510. Email: AKR_ Regulations@nps.gov.

SUPPLEMENTARY INFORMATION: On May 22, 2018, the National Park Service (NPS) published in the **Federal Register** (83 FR 23621) a proposed rule to amend

its regulations for sport hunting and trapping in National Preserves in Alaska. This proposed rule would remove a regulatory provision issued by the NPS in 2015 that prohibited certain sport hunting practices that are otherwise permitted by the State of Alaska. These proposed changes are consistent with Secretary of the Interior Orders 3347 and 3356. The public comment period for this proposal is scheduled to close on July 23, 2018. In order to give the public additional time to review and comment on the proposal, the NPS is extending the public comment period for 45 days until September 6, 2018. If you already commented on the proposed rule you do not have to resubmit your comments.

P. Daniel Smith,

 $\label{lem:potential} \textit{Deputy Director, Exercising the Authority of the Director.}$

[FR Doc. 2018–15420 Filed 7–18–18; 8:45 am] BILLING CODE 4310–EJ–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R10-OAR-2018-0505; FRL-9981-01-Region 10]

Air Plan Approval; Oregon; Interstate Transport Requirements for the 2012 PM_{2.5} NAAQS

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Clean Air Act (CAA) requires each State Implementation Plan (SIP) to contain adequate provisions prohibiting emissions that will have certain adverse air quality effects in other states. On October 20, 2015, the State of Oregon made a submission to the Environmental Protection Agency (EPA) to address these requirements. The EPA is proposing to approve the submission as meeting the requirement that each SIP contain adequate provisions to prohibit emissions that will contribute significantly to nonattainment or interfere with maintenance of the 2012 annual fine particulate matter (PM_{2.5}) national ambient air quality standard (NAAQS) in any other state.

DATES: Comments must be received on or before August 20, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R10-OAR-2018-0505 at https://www.regulations.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be

edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit https://www.epa.gov/dockets/ commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, Air Planning Unit, Office of Air and Waste (OAW–150), Environmental Protection Agency, Region 10, 1200 Sixth Ave., Suite 155, Seattle, WA 98101; telephone number: (206) 553–0256; email address: hunt.jeff@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean the EPA. This supplementary information section is arranged as follows:

Table of Contents

- I. What is the background of this SIP submission?
- II. What guidance or information is the EPA using to evaluate this SIP submission?

 III. The EPA's Review
- IV. What action is the EPA taking?
 V. Statutory and Executive Order Reviews

I. What is the background of this SIP submission?

This rulemaking addresses a submission from the Oregon Department of Environmental Quality (ODEQ) assessing interstate transport requirements for the 2012 annual PM_{2.5} NAAQS. The requirement for states to make a SIP submission of this type arises from section 110(a)(1) of the CAA. Pursuant to section 110(a)(1), states must submit within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof), a plan that provides for the implementation, maintenance, and enforcement of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions,

and the requirement to make the submissions is not conditioned upon the EPA taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that "[e]ach such plan" submission must address. The EPA commonly refers to such state plans as "infrastructure SIPs." Specifically, this rulemaking addresses the requirements under CAA section 110(a)(2)(D)(i)(I), otherwise known as the "good neighbor" provision, which requires SIPs to contain adequate provisions to prohibit emissions that will contribute significantly to nonattainment or interfere with maintenance of the NAAQS in any other state.

II. What guidance or information is the EPA using to evaluate this SIP submission?

The most recent relevant document was a memorandum published on March 17, 2016, titled "Information on the Interstate Transport "Good Neighbor" Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I)(memorandum). The memorandum describes the EPA's past approach to addressing interstate transport, and provides the EPA's general review of relevant modeling data and air quality projections as they relate to the 2012 annual PM_{2.5} NAAQS. The memorandum provides information relevant to the EPA regional office review of the CAA section 110(a)(2)(D)(i)(I) "good neighbor" provision in infrastructure SIPs with respect to the 2012 annual PM_{2.5} NAAQS. This rulemaking considers information provided in that memorandum.

The memorandum also provides states and the EPA regional offices with future year annual PM_{2.5} design values for monitors in the United States based on quality assured and certified ambient monitoring data and air quality modeling. The memorandum describes how these projected potential design values can be used to help determine which monitors should be further evaluated to potentially address whether emissions from other states significantly contribute to nonattainment or interfere with maintenance of the 2012 annual PM_{2.5} NAAQS at those sites. The memorandum explains that the pertinent year for evaluating air quality for purposes of addressing interstate transport for the 2012 PM_{2.5} NAAQS is 2021, the attainment deadline for 2012

 $PM_{2.5}$ NAAQS nonattainment areas classified as Moderate.

Based on this approach, the potential receptors are outlined in the memorandum. Most of the potential receptors are in California, located in the San Joaquin Valley or South Coast nonattainment areas. However, there is also one potential receptor in Shoshone County, Idaho, and one potential receptor in Allegheny County, Pennsylvania. The memorandum also indicates that for certain states with incomplete ambient monitoring data, additional information including the latest available data should be analyzed to determine whether there are potential downwind air quality problems that may be impacted by transported emissions.

This rulemaking considers analysis in Oregon's submission, as well as additional analysis conducted by the EPA during review of its submission. For more information on how we conducted our analysis, please see the technical support document (TSD) included in the docket for this action.

III. The EPA's Review

This rulemaking proposes action on Oregon's October 20, 2015, SIP submission addressing the good neighbor provision requirements of CAA section 110(a)(2)(D)(i)(I). State plans must address specific requirements of the good neighbor provisions (commonly referred to as "prongs"), including:

- —Prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong one); and
- —Prohibiting any source or other type of emissions activity in one state from interfering with maintenance of the NAAQS in another state (prong two).

The EPA has developed a consistent framework for addressing the prong one and two interstate transport requirements with respect to the PM_{2.5} NAAOS in several previous federal rulemakings. The four basic steps of that framework include: (1) Identifying downwind receptors that are expected to have problems attaining or maintaining the relevant NAAQS; (2) identifying which upwind states contribute to these identified problems in amounts sufficient to warrant further review and analysis; (3) for states identified as contributing to downwind air quality problems, identifying upwind emissions reductions necessary to prevent an upwind state from significantly contributing to nonattainment or interfering with

maintenance of the relevant NAAQS downwind; and (4) for states that are found to have emissions that significantly contribute to nonattainment or interfere with maintenance of the relevant NAAQS downwind, reducing the identified upwind emissions through adoption of permanent and enforceable measures. This framework was applied with respect to PM_{2.5} in the Cross-State Air Pollution Rule (CSAPR), designed to address both the 1997 and 2006 PM_{2.5} standards, as well as the 1997 ozone standard.¹

In its submission, ODEQ reviewed air quality monitoring data for several surrounding western states to identify potential downwind receptors that may have problems attaining or maintaining the 2012 PM_{2.5} NAAQS. ODEQ then reviewed geographical distance, topography, meteorology (local stagnation events), air monitoring trends, industrial source emissions near the state border, and Western Regional Air Partnership (WRAP) modeling to determine if emissions from Oregon may impact these specific areas. From this analysis and consultation with neighboring state air agencies, ODEQ concluded that Oregon does not significantly contribute to nonattainment or interfere with maintenance of the 2012 PM_{2.5} NAAQS in any other state.

As discussed in the TSD for this action, we came to the same conclusion as the state. In our evaluation, potential downwind nonattainment and maintenance receptors were identified in other states. The EPA evaluated these potential receptors to determine first if, based on review of relevant data and other information, there would be downwind nonattainment or maintenance problems, and if so, whether Oregon contributes to such problems in these areas. After reviewing air quality reports, modeling results, designation letters, designation technical support documents, attainment plans and other information for these areas, we find there is no contribution sufficient to warrant additional SIP measures. Therefore, we are proposing to approve the Oregon SIP as meeting CAA section 110(a)(2)(i)(I) interstate transport requirements for the 2012 PM_{2.5} NAAQS.

IV. What action is the EPA taking?

The EPA is proposing to approve ODEQ's October 20, 2015, submission certifying that the Oregon SIP is sufficient to meet the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I), specifically prongs one and two, as set forth above. The EPA is requesting comments on the proposed approval.

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 CAA 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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).

List of Subjects in 40 CFR Part 52

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

Dated: July 3, 2018.

Chris Hladick,

Regional Administrator, Region 10. [FR Doc. 2018–15353 Filed 7–18–18; 8:45 am] BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[MB Docket No. 18-119; DA 18-669]

FM Translator Interference: Media Bureau Grants Extension of Time To File Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document announces that the Media Bureau of the Federal Communications Commission granted the Motion for Extension of Time to extend the comment and reply comment deadlines, filed by Beasley Media Group, LLC; Educational Media Foundation; Gradick Communications, LLC; iHeart Communications, Inc.; Neuhoff Corp.; Radio One Licenses, LLC/Urban One, Inc.; and Withers Broadcasting Companies (Petitioners), in MB Docket 18–119.

DATES: Comments may be filed on or before August 6, 2018, and reply comments may be filed on or before September 5, 2018.

ADDRESSES: You may submit comments, pursuant to Sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, by any of the following methods:

 $^{^1}$ Oregon was not part of the CSAPR rulemaking. The EPA approved the Oregon SIP as meeting the CAA section 110(a)(2)(D)(i)(I) requirements for the 1997 ozone and 1997 PM $_{2.5}$ NAAQS on June 9, 2011 (76 FR 33650) and the 2006 PM $_{2.5}$ NAAQS on January 16, 2015 (80 FR 2313).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- 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 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington DC 20554.
- People with Disabilities: Contact the FCC to request reasonable accommodations (accessible format

documents, sign language interpreters, CART, etc.) by email: FCC504@fcc.gov or phone: (202) 418–0530 or TTY: (202) 418–0432. For detailed instructions on submitting comments and additional information on the rulemaking process, see the Commission's Notice of Proposed Rulemaking, MB Docket No. 18–119, FCC 18–60, adopted May 10, 2018, and released May 10, 2018.

FOR FURTHER INFORMATION CONTACT:

Albert Shuldiner, Chief, Audio Division, Media Bureau, (202) 418–2721; James Bradshaw, Deputy Division Chief, Media Bureau (202) 418–2739. Direct press inquiries to Janice Wise at (202) 418–8165.

SUPPLEMENTARY INFORMATION: This is a summary of the Media Bureau's Order. DA 18-669, adopted June 27, 2018, and released June 27, 2018. Petitioners filed a Motion for Extension of Time seeking to extend the deadlines to file comments and reply comments to August 6, 2018, and September 5, 2018, respectively, in FM Translator Interference, Notice of Proposed Rulemaking, MB Docket No. 18-119, FCC 18-60 (rel. May 10, 2018), 83 FR 26229, June 6, 2018. For good cause shown, the Media Bureau, pursuant to delegated authority, granted the request. Comments were originally due July 6, 2018, and reply comments on August 6, 2018. Grant of the request makes comments due on August 6, 2018, and reply comments due on September 5, 2018. This proceeding is treated as "permit but disclose" for purposes of the Commission's ex parte rules. See generally 47 CFR 1.200-1.216. As a result of the permit but disclose status of this proceeding, ex parte

presentations will be governed by the procedures set forth in Section 1.1206 of the Commission's rules applicable to non-restricted proceedings.

The full text of this document is available electronically via the FCC's Electronic Document Management System (EDOCS) website at http:// https://www.fcc.gov/edocs or via the FCC's Electronic Comment Filing System (ECFS) website at http://https:// www.fcc.gov/ecfs/. (Documents will be available electronically in ASCII, Microsoft Word, and/or Adobe Acrobat.) This document is also available for public inspection and copying during regular business hours in the FCC Reference Information Center, which is located in Room CY-A257 at FCC Headquarters, 445 12th Street SW, Washington, DC 20554. The Reference Information Center is open to the public Monday through Thursday from 8:00 a.m. to 4:30 p.m. and Friday from 8:00 a.m. to 11:30 a.m. The complete text may be purchased from the Commission's copy contractor, 445 12th Street SW, Room CY-B402, Washington, DC 20554. 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).

Federal Communications Commission.

James Bradshaw,

Deputy Chief, Audio Division, Media Bureau. [FR Doc. 2018–15275 Filed 7–18–18; 8:45 am] BILLING CODE 6712–01–P

Notices

Federal Register

Vol. 83, No. 139

Thursday, July 19, 2018

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Meeting: Board for International Food and Agricultural Development

Pursuant to the Federal Advisory Committee Act, notice is hereby given of the public meeting of the Board for International Food and Agricultural Development (BIFAD). The meeting will be held from 9:00 a.m. to 12:00 p.m. ET on Wednesday, August 8, 2018, at the Madison A&B on the Mezzanine Level, Marriott Wardman Park Hotel, 2660 Woodley Rd. NW, Washington, DC. Participants may attend in person or join via livestream. The link to the global live stream as well as registration information can be found on BIFAD's home page: http://www.usaid.gov/bifad.

The central theme of this public meeting will be US Benefits Leveraged from Strategic Investments in Developing Country Agriculture and Food Security. Dr. Mark Keenum, BIFAD Chair, will preside over the public business meeting, which will begin promptly at 9:00 a.m. ET with opening remarks. At this meeting the Board will address old and new business, and then invite Agricultural & Applied Economics Association members and other interested individuals to engage in a dialogue and provide feedback on a new study that is being commissioned by BIFAD and USAID. This study will conduct a metaanalysis of US benefits and capabilities that are leveraged from strategic investments in developing country agriculture and food security. Presenting at the meeting is Dr. Joseph Glauber, Senior Research Fellow at the International Food Policy Research Institute (IFPRI), who is leading the study for BIFAD. Dr. Glauber served over 30 years at the US Department of Agriculture, including as Chief Economist from 2008 to 2014.

Beginning at 11:15 a.m. ET, Chairman Keenum will moderate a half-hour public comment period. The public meeting will adjourn at 12:00 p.m. ET with Dr. Keenum's closing remarks.

Those wishing to attend the meeting or obtain additional information about BIFAD should contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Food Security at USAID. Interested persons may write to her in care of the U.S. Agency for International Development, Ronald Reagan Building, Bureau for Food Security, 1300 Pennsylvania Avenue NW, Washington, DC 20523–2110 or telephone her at (202) 712–0119.

Clara Cohen,

Designated Federal Officer, BIFAD, Bureau for Food Security, U.S. Agency for International Development.

[FR Doc. 2018–15413 Filed 7–18–18; 8:45 am] **BILLING CODE P**

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

Notice of Funds Availability (NOFA) for the Conservation Reserve Program (CRP) Forest Inventory Analysis Pilot

AGENCY: Commodity Credit Corporation and Farm Service Agency, U.S. Department of Agriculture (USDA). **ACTION:** Notice.

SUMMARY: The Farm Service Agency (FSA), on behalf of Commodity Credit Corporation (CCC), is announcing the availability of competitive grants to conduct a forest inventory analysis, forest management, and economic outcomes modelling, for certain currently enrolled Conservation Reserve Program (CRP) land. The analysis is focused on lands enrolled in CRP for at least 8 years and located in areas with a substantial concentration of acres enrolled under the following conservation practices devoted to multiple bottomland hardwood tree species: General tree planting, hardwood tree planting, vegetative cover on previously established tree stands, riparian buffers, bottomland timber establishments, and farmable and aquaculture wetlands. Qualified applicants must be non-profit organizations dedicated to conservation, forestry, and wildlife habitats that have experience in conducting accurate forest inventory analysis through the use of advanced, cost-effective technology, as determined by FSA.

DATES: Application Deadline: August 15, 2018.

ADDRESSES: Applications must be submitted in the following method: *Grants Portal:* Go to *www.grants.gov.* Follow the online instructions for submitting grants.

FOR FURTHER INFORMATION CONTACT: Richard Iovanna, telephone (202) 720– 5291

SUPPLEMENTARY INFORMATION:

Background

Section 743 of the Consolidated Appropriations Act, 2018 (Pub. L. 115–141) requires that the USDA enter into grant agreements for forest inventory analysis, and forest management, and economic outcomes modelling of certain CRP land. Under this authority, the CCC will make available not more than \$1 million in grants to non-profit organizations. The CRP Forest Inventory Analysis Pilot will be administered under the general supervision of FSA on behalf of CCC, in accordance with the provisions of 2 CFR part 200.

Description

The CRP Forest Inventory Analysis Pilot is focused on lands enrolled in CRP for at least 8 years and located in areas with a substantial concentration of acres enrolled under certain conservation practices devoted to multiple bottomland hardwood tree species, including conservation practices for general tree planting, hardwood tree planting, vegetative cover on previously established tree stands, riparian buffers, bottomland timber establishments, and farmable and aquaculture wetlands. Qualified applicants must be non-profit organizations dedicated to conservation, forestry, and wildlife habitats that have experience in conducting accurate forest inventory analysis through the use of advanced, cost-effective technology.

Comprehensive data analysis using advanced, cost-effective technology on land enrolled in CRP with certain bottomland hardwood practices is important for several reasons. Such data will provide the FSA CRP program manager with the information needed to more effectively manage enrollment. For example, the inventory may find that mortality of a selected species of tree is

high in certain situations. As a result, the CRP program manager may adjust what tree species can be enrolled in CRP on a regional and site-specific basis. Economic modeling will provide information on the expected net returns to CRP enrollees, as well as an evaluation of taxpayer costs. In short, there is a need for data collection and analysis of bottomland hardwood conservation practices and economics.

For more than 30 years under CRP, landowners have voluntarily enrolled tens of millions of farmland acres to conserve and improve soil, protect

water quality, and provide wildlife habitat by establishing long-term cover, primarily grasses and trees. Landowners voluntarily enroll their lands for periods of between 10 and 15 years.

CRP cost share funding is provided to landowners who install the prescribed conservation practices. These practices can be costly and require ample investment by the landowner and technical assistance provider to ensure that the practices are appropriate and properly installed. The adequacy of the conservation plan is paramount to

achieving CRP enrollment goals, especially for bottomland hardwoods.

Bottomland hardwoods are streamside forest trees—such as cottonwood, sycamore, oak, maple, ash, cypress, and tupelo—that typically grow on lands prone to flooding. Over the past 8 years, 46 States have enrolled land into CRP that is devoted to bottomland hardwood trees. Cumulative CRP bottomland hardwood tree enrollment, over the past 8 years, is just over 799,000 acres, with over 550,000 acres (69 percent) located in the States shown in Table 1.

TABLE 1—TREE ENROLLMENT IN CRP BY STATE OVER THE PAST 8 YEARS; USDA MAY 31, 2018

| State | Total CRP tree acres | Cumulative acres | Acres of total percent | Region |
|----------------|----------------------|------------------|------------------------|-------------------|
| Mississippi | 204,870 | 204,870 | 26 | Southern Forest. |
| Arkansas | 79,341 | 284,211 | 36 | Southern Forest. |
| Louisiana | 75,087 | 359,298 | 45 | Southern Forest. |
| Alabama | 58,035 | 417,333 | 52 | Southeast Forest. |
| Illinois | 47,824 | 465,156 | 58 | Midwest Forest. |
| Georgia | 35,212 | 500,369 | 63 | Southeast Forest. |
| North Carolina | 26,942 | 527,310 | 66 | Southeast Forest. |
| Minnesota | 24,346 | 551,674 | 69 | Northern Forest. |

The CRP Forest Inventory Analysis Pilot is intended to provide information and analysis needed to better inform CRP decision making associated with the following bottomland hardwood conservation and stand maintenance practices:

- CP03—Tree Planting;
- 2. CP03A—Hardwood Tree Planting;
- 3. CP11—Vegetative Cover—Trees Already Established; 1
 - 4. CP22—Riparian Buffer;
- 5. CP31—Bottomland Timber
- Establishment; and

6. CP40—Farmable Wetland Program—Aquaculture Wetland.

The inventory, analysis, and modeling must estimate, at a minimum, stand composition, stand density, basal area, and tree height using remotely sensed data (rather than data collected by visiting a site). The data will be used to generate statistically robust estimates of commercial value, economic returns, carbon sequestration, and wildlife and water quality impacts for each of the practices in at least one of the regions and states enumerated in Table 1. These estimates will identify species appropriate for bottomland CRP practices or sites, as well as forest management practices needed to maintain cover during the contract

period. An accurate assessment of the model output will be conducted using ground plots.

Definitions

The 2018 Consolidated Appropriations Act uses the term "nonprofit organizations." Consistent with OMB Circular A-122, the term "nonprofit organization" means any corporation, trust, association, cooperative, or other organization that:

- 1. Is operated primarily for scientific. educational, service, charitable, or similar purposes in the public interest;
- 2. Is not organized primarily for profit; and
- 3. Uses its net proceeds to maintain, improve, or expand its operations.

The term "non-profit organization"

- 1. Colleges and universities, unless a 501(c)(3) has been established;
 - 2. Hospitals;
- 3. State, local, and federallyrecognized Indian tribal governments;
- 4. Those non-profit organizations that are excluded from coverage under paragraph 5 of Office of Management and Budget (OMB) Circular A–122.

The term "economic outcomes modelling" as used in this NOFA, must include multiple dimensions, including, but not limited to, baseline return estimates to CRP participants (taking into account, among other items, commercial value), and returns under

alternative scenarios that reflect management recommendations.

Eligibility and Application Process

Non-profit organizations dedicated to conservation, forestry, and wildlife habitats, that have experience in conducting forest inventory analysis through the use of remote sensing data and technology are eligible to apply. Applicants must submit an application by August 15, 2018, through www.grants.gov. To find the CRP Forest Inventory Analysis Pilot in www.grants.gov, search on funding opportunity number USDA-FSA-CRPFIA-2018. Applications must include, but are not limited to, an executive summary, work plan, and budget information using Application for Federal Assistance (SF-424) form. (See www.grants.gov for more details about the specific application requirements.)

Non-profit organizations may submit a combined cross-organization proposal to include work that will be coordinated across more than one organization, especially if a joint proposal creates synergies or increased efficiencies. The application may include one or more forest regions.

The result of a successful application will be a one-time grant agreement. Successful applicants will be required to sign the grant agreement with FSA, which will include reporting and recordkeeping requirements. It is possible that not all of the \$1 million

¹ The purpose of the CP11 practice is to maintain a stand of trees in a timber planting previously established on cropland as practice CP-3 or CP-3A to enhance environmental benefits. This CP11 practice was available only through a re-offer of expiring or expired CRP acres.

authorized by Congress for this pilot will be expended. All applications are subject to the approval of FSA, and FSA reserves the right to reject any and all applications.

Application Selection Criteria

FSA will evaluate applications using the evaluation criteria specified in this NOFA and on *www.grants.gov* to select the application(s) that best support the goals of CRP Forest Inventory Analysis Pilot. A proposal must include the following information; this information will be used by FSA in the awarding of grants:

- 1. Amount of funding requested;
- 2. Amount of funding from other parties (with sufficient documentation) that provide additional leverage, if any; for example, specifying the regions, states, practices and plots where the proposal goes beyond minimal requirements (such as by considering CP–36, long-leaf pine);
 - 3. Sampling approach to be used;
- 4. Remotely sensed data to be used, including its sources and its spatial, temporal, and spectral resolution;
- 5. Number and relevance of metrics to be estimated and the modeling approach to be used to estimate the metrics;
- 6. The accuracy assessment, including sampling approach and location of ground plots following the U.S. Forest Service's Common Stand Examination protocols or those in the peer-reviewed literature; and
- 7. Work plan and timeline for completion by September 30, 2020.

Process for Evaluation and Application and Awards of Grants

After applicants submit applications, FSA, on behalf of CCC, will screen each application to determine whether the applicant is eligible and whether the application is complete and sufficiently responsive to the requirements specified in this NOFA. Applicants may revise their applications and re-submit them prior to the published deadline if there is sufficient time to do so. FSA will appoint an inter-agency review panel to evaluate the applications. During the evaluation period, FSA may contact an applicant to seek clarification and modification of the proposal. The resulting CRP Forest Inventory Analysis Pilot grant agreements will be between the non-profit organization(s) and FSA.

Any non-profit organization that receives a grant must commit to fully expend the awarded federal funds by September 30, 2020, with an opportunity for extension upon approval by FSA.

Responsibilities of the Participants

Successful applicants will be required to sign an agreement with FSA and provide detailed budget and schedule information. The agreement will require periodic achievement reports. The agreement will require the grantee to commit to do all of the following:

- 1. Perform inventory, analysis, modelling and validating, including conducting site visits and plot sampling, on the CRP enrolled acreage; and
- 2. Provide an accounting for the money received by the grantee.

During the term of the grant, the grantee will be required to obtain prior approval for any changes to the scope, objectives, or funding allocation of the approved agreement. Failure to obtain prior approval of such changes may be considered a violation, and in such case the grantee may be required to return all grant funds, including any funds already expended, as determined appropriate by FSA. Grantees will be required to monitor funds and report on expenditures. The grantee must certify that the CCC funds will not be used to:

- 1. Duplicate existing inventories, analysis, or economic modelling efforts; however, grant funds may be used to expand the prior inventories, analysis, or economic modelling efforts;
- 2. Pay costs of preparing a CRP Forest Inventory Analysis Pilot grant application;
- 3. Pay costs of the project incurred prior to the date of grant approval;
- 4. Fund political activities or lobbying efforts:
- 5. Pay any judgment or debt owed to the United States;
- 6. Pay for the repair of privately owned vehicles;
- 7. Pay for unrelated salaries, overhead, and expenses; or
 - 8. Pay for unrelated research.

Failure of the grantee to execute a grant agreement in a timely fashion, as determined by FSA, will be construed to be a withdrawal from the CRP Forest Inventory Analysis Pilot. In this event, FSA will demand a refund of the grant funds as deemed appropriate by FSA.

Distribution of Grant Funds and Reimbursement of Unused Funds

FSA expects to transfer CCC funds to the selected non-profit organization applicants before September 30, 2018.

Environmental Review

The environmental impacts of this NOFA have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on

Environmental Quality (40 CFR parts 1500 through 1508), and the FSA regulations for compliance with NEPA (7 CFR part 799).

The purpose of the grants for the CRP Forest Inventory Analysis Pilot is to provide the CRP Program Manager with information to inform decision-making about the effectiveness of certain conservation practices on CRP land for bottomland hardwoods and are passive in nature and will not involve ground disturbance or tree removals or disturbance. The discretionary aspects of the CRP Forest Inventory Analysis Pilot include, but are not limited to, eligibility, how many grants to award, and how to evaluate submissions. As such, the Categorical Exclusions in 7 CFR 799.31 apply, specifically 7 CFR 799.31(b)(6)(vii) and (viii) (these two categorical exclusions include site characterization, environmental testing, and monitoring where no significant alteration of existing ambient conditions would occur; and, stand analysis for forest management planning, respectively). No "Extraordinary circumstances" (7 CFR 799.33) exist; as such, FSA has determined that this NOFA does not constitute a major Federal action that would significantly affect the quality of the human environment, individually or cumulatively. Therefore, beyond this Environmental Review in this NOFA, FSA will not prepare any additional environmental documentation for this

Paperwork Reduction Act Requirements

The CRP Forest Inventory Analysis Pilot is exempt from the requirements of the Paperwork Reduction Act (44 U.S.C. Chapter 35), as amended, as specified in subsection 1601(c)(2)(B) of the Agricultural Act of 2014 (the 2014 Farm Bill, 16 U.S.C. 3846(b)), which provides that CRP, as a Title II program, be promulgated and administered without regard to the Paperwork Reduction Act.

Catalog of Federal Domestic Assistance

The title and number of the Federal assistance in the Catalog of Federal Domestic Assistance to which this NOFA applies is 10.122, the Conservation Reserve Program (CRP) Forest Inventory Analysis Pilot.

Richard Fordyce,

Administrator, Farm Service Agency.
[FR Doc. 2018–15349 Filed 7–18–18; 8:45 am]

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2018-0021]

Notice of Request for a New Information Collection: (Consumer Research on the Safe Handling Instructions Label for Raw and Partially Cooked Meat and Poultry Products and Labeling Statements for Ready-to-Eat and Not-Ready-to-Eat Products)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to collect information in the form of consumer research that will include a web-based experimental study and a behavior change study to help inform potential revisions to the current Safe Handling Instructions (SHI) label and assess whether a label revision would improve consumer food safety behaviors. FSIS also will collect information on consumer use and understanding of the labeling on readyto-eat (RTE) and not-ready-to-eat (NRTE) meat and poultry products, in particular consumers' ability to discern between the two types of products and to ensure that NRTE products that may appear to be ready to eat are thoroughly cooked. **DATES:** Submit comments on or before

September 17, 2018.

ADDRESSES: FSIS invites interested

persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

• Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.

• Mail, including CD–ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.

• Hand- or courier-delivered submittals: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the

Agency name and docket number FSIS–2018–0021. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Title: Consumer Research on the Safe Handling Instructions Label for Raw and Partially Cooked Meat and Poultry Products and Labeling Statements for Ready-to-Eat and Not-Ready-to-Eat Products.

Type of Request: New information collection.

Abstract: Safe handling instructions are required on the labels of raw or partially-cooked (i.e., not considered RTE) meat and poultry products, if the product is destined for household consumers or institutional uses (9 CFR 317.2(l) and 9 CFR 381.125(b)). FSIS first required the SHI label for raw and partially cooked meat and poultry products in 1994 (54 FR 14528). Since that time, the required design of the SHI label has not been changed.

When the SHI label was developed in 1994, the minimal internal temperature requirements for determining whether a meat or poultry product was cooked enough to be safe varied by product. Given this, as well as product and label size limitations. FSIS concluded that "Cook Thoroughly" was the only simple, single statement appropriate to use for all products (54 FR 14538). FSIS now recommends on its website four internal minimal temperatures: One for all poultry (165 °F), one for ground meat (160 °F), one for all whole-muscle meat (145 °F and hold for 3 minutes), and one for fish (145 °F). With only four temperature recommendations, the information could be more easily incorporated into the SHI requirements. Other possible changes to the SHI label include incorporating updated icons and providing a web link or phone number for more information.

In response to inquiries from consumer groups and other stakeholders about potential changes to SHI requirements, FSIS gathered input from members of academia, industry, and consumer stakeholders in November 2013. FSIS presented these suggestions to the National Advisory Committee on Meat and Poultry Inspection (NACMPI) in January 2014. The NACMPI Subcommittee on Food Handling Labels recommended that FSIS pursue changes in the existing SHI label and conduct consumer research to determine the effectiveness of any revisions to the SHI label.

In 2015, FSIS conducted six consumer focus groups (OMB No. 0583-0166; 11/ 30/2017) to evaluate understanding of the current SHI label and responses to possible revisions. The focus groups revealed that consumers would find certain revisions to the SHI label useful. Participants suggested changes to improve comprehension and adherence to recommended safe handling practices (e.g., add recommendations to use a food thermometer and endpoint temperatures for different cuts of meat and poultry). Based on the results of these focus groups, FSIS determined that additional research using more rigorous, quantitative approaches with a larger sample of consumers was needed to help inform potential revisions to the current SHI label and assess whether a label revision would improve consumer food safety behaviors.

In addition, during the March 2016 NACMPI meeting, the national advisory committee reviewed and discussed whether FSIS should pursue proposing mandatory features on the label of processed NRTE products that may appear to be fully cooked (e.g., are breaded or have grill marks). The committee recommended that FSIS require statements, such as "Raw, "Uncooked," or "Ready to Cook," on the labels of raw products that may appear RTE, so it is clear that these products require cooking to a proper internal temperature before eating. The committee also recommended that FSIS conduct consumer research to understand the optimal messaging and design of packaging to ensure consumers properly understand that NRTE products that may appear to be fully cooked need to be cooked for lethality. The committee stated that such labeling may help consumers properly distinguish between NRTE products, which require a lethality step, and RTE products, which do not require a lethality step; thus, the committee stated that this labeling may help consumers safely prepare NRTE products. Specifically, the committee suggested that FSIS conduct consumer research to evaluate the effectiveness of possible locations for point of purchase labeling information and various color

options, font, and other display options. FSIS has not previously conducted research on this topic.

To assess whether revisions are needed to the SHI label required on all raw and partially cooked products and to evaluate the ability of consumers to properly discern between NRTE and RTE products and how labeling for these products can be improved, FSIS is requesting approval for a new information collection to conduct consumer behavior research. This research will include a web-based experimental study, as well as a behavior change study, which includes three components: An observational meal preparation experiment, an eyetracking study, and in-depth interviews (IDIs). The research will help inform potential revisions to the current SHI label and assess whether a label revision would be likely to improve consumer behaviors related to safely preparing raw and partially cooked meat and poultry products. The study will also collect information on consumer use and understanding of labeling for RTE and NRTE meat and poultry products.

FSIS has contracted with RTI International to conduct the web-based experimental study and the behavior change study. For the web-based experimental study, a selected sample of online consumer panel members will be invited to participate in the study via email. Inbound sampling will be used to select a sample of respondents with demographic characteristics (e.g., age, education level, race, and ethnicity) similar to the U.S. population. The primary aim of the web-based experimental study is to test 25 mock SHI labels that vary by visual design elements (e.g., borders, white space, spatial arrangement) to determine which labels are most salient to consumers. Label salience (i.e., participants' degree of attention to the label) will be assessed using a limited-time exposure approach with cued recall questions. Secondary aims of the study include assessing comprehension of safe handling instructions and safe handling icons and measuring the participants' motivation to comply with safe handling messages. The data from the experimental study will be analyzed to identify the five SHI labels that best attract respondents' attention, and from these, three labels will be selected for further testing in the behavior change study.

To assess and compare consumer behavior in response to the current SHI label (control) and the three alternative

SHI labels, a behavior change study will be conducted in test kitchen facilities located in four different locations (one in each of four Census regions). Participants will be recruited using convenience sampling (e.g., by posting ads on social media). The study will ensure a diverse sample of participants with respect to race, ethnicity, age, education level, and presence of a child (0-17 years) in the household. The study will use a fully randomized experimental design with participants randomly assigned to one of three treatment groups (that will be used to assess three alternative SHIs) or a control group (that will be used to assess the current SHI). Participants will be given recipes and ingredients, including two raw meat products bearing the assigned SHI label and asked to prepare two meat dishes and a salad. To assess attention to the SHI label during meal preparation, participants will wear a mobile eyetracking device. Research staff will video-record meal preparation and clean-up. Trained researchers will subsequently view the videos and use a coding rubric to assess adherence to the recommended safe handling instructions (e.g., washing hands before meal preparation and after touching raw meat). Statistical analysis comparing the differences in handling behavior scores between the control (current SHI label) and treatment groups will be conducted to identify the label that may most effectively lead to participants' following the safe handling practices on the label.

Following meal preparation, participants will be directed to examine each of six mock meat and poultry products (i.e., stimuli) while wearing the eye-tracking device: Two RTE products, two NRTE products that appear ready to eat, and two raw products. Participants will be asked to complete a series of search tasks to determine which version of the SHI label (three treatment versions or the current label) is most often attended to on a meat and poultry package and to assess whether participants can properly distinguish between RTE and NRTE products that appear to be ready to eat. Eye-tracking metrics for each area of interest (AOI), including total time spent viewing each AOI, will be produced and used in statistical analyses to determine the label that best captures participants' attention.

Lastly, participants will take part in an IDI and be asked debriefing questions regarding the meal preparation experiment and questions to understand how consumers determine whether a meat or poultry product needs to be cooked before eating it. The data will be analyzed by analysts using a thematic content analysis approach.

Estimate of Burden: For the pretest for the web-based experimental study, it is expected that 1,700 individuals will receive email invitations to complete the study and that 100 will be eligible and subsequently complete the study. For the web-based experimental study, it is expected that 70,000 individuals will receive email invitations to complete the study and that 3,600 will be eligible and subsequently complete the study. The invitation email for the pretest and the full-scale study is expected to take 2 minutes to read (0.033 hour). The survey is expected to take 20 minutes to complete. The total estimated burden of the web-based experimental study is 3,623.3 hours.

For the behavior change study, it is expected that 1,695 individuals will complete the screener and that 565 will be eligible and subsequently be contacted by phone to schedule an appointment. Of these, it is assumed that 480 will take part in the study. Each screening is expected to take 8 minutes (0.133 hour). It is expected to take 7 minutes (0.117 hour) to read or listen to each appointment call/confirmation email/reminder call. It is expected to take 10 minutes (0.167 hour) to read the informed consent form and watch the instructional video. Taking part in the behavior change study will take a total of 140 minutes (2.333 hours), which includes an observational meal preparation experiment (80 minutes), an eye-tracking component (30 minutes), and IDIs (30 minutes). The estimated annual reporting burden for the behavior change study is 1,491.9 hours, which is the sum of the burden estimates for each component of the study (including the burden for individuals who initially complete the screener but are not eligible or do not agree to participate).

For all components of the information collection, the estimated total number of individuals to be screened is 73,395, and the estimated total number of individuals to complete the web-based experimental study, including pretest, and the behavior change study is 4,180. The estimated total burden for the information collection is 5,115.2 hours.

ESTIMATED ANNUAL REPORTING BURDEN FOR THE WEB-BASED EXPERIMENTAL STUDY AND THE BEHAVIOR CHANGE STUDY

| Study component | Estimated Number of respondents | Annual frequency per response | Total annual responses | Hours per response | Total hours |
|--|---------------------------------------|-------------------------------------|------------------------|--------------------|-------------|
| | Web-Based Ex | perimental Stud | у | | |
| Pretest invitation | 1,700 | 1 | 1,700 | 0.033 (2 min.) | 56.7 |
| Pretest | 100 | 1 | 100 | 0.333 (20 min.) | 33.3 |
| Survey invitation | 70,000 | 1 | 70,000 | 0.033 (2 min.) | 2,333.3 |
| Survey | 3,600 | 1 | 3,600 | 0.333 (20 min.) | 1,200.0 |
| Total | | | | | 3,623.3 |
| | Behavior C | hange Study | | | |
| Screening questionnaire | 1,695 | 1 | 1,695 | 0.133 (8 min.) | 226.0 |
| Appointment phone script, confirmation email, reminder phone script. | 565 | 1 | 565 | | 65.9 |
| Consent form and video | 480 | 1 | 480 | 0.167 (10 min.) | 80.0 |
| Meal Preparation, eye-tracking & in-depth interviews | 480 | 1 | 480 | 2.333 (140 min.) | 1,120.0 |
| Total | | | | | 1,491.9 |
| Total | | | | | 5,115.2 |

Respondents: Consumers.
Estimated Number of Respondents: 73.395.

Estimated Number of Annual Responses per Respondent: 1. Estimated Total Burden on Respondents: 5,115.2 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

Responses to this notice will be summarized and included in the request

for OMB approval. All comments will also become a matter of public record.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation,

disability, age, marital status, family/ parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program
Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Paul Kiecker,

Acting Administrator. [FR Doc. 2018–15462 Filed 7–18–18; 8:45 am] BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service [Docket No. FSIS-2018-0020]

Notice of Request for a New Information Collection: Food Defense Vulnerability Questionnaire

AGENCY: Food Safety and Inspection

Service, USDA.

ACTION: Notice and request for

comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to collect information from food industry and academic experts on vulnerabilities and research activities related to food defense for FSIS-regulated food products. The purpose of this information collection is to inform FSIS food defense efforts to help protect against an intentional attack on the food supply.

DATES: Submit comments on or before September 17, 2018.

ADDRESSES: FSIS invites interested persons to submit comments on this **Federal Register** notice. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to http://www.regulations.gov. Follow the on-line instructions at that site for submitting comments.
- Mail, including CD–ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- Hand- or courier-delivered submittals: Deliver to 1400

Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS—2018—0020. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to http://www.regulations.gov.

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

SUPPLEMENTARY INFORMATION:

Title: Food Defense Vulnerability Questionnaire

Type of Request: New information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, et seq.). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS's Office of Data Integration and Food Protection (ODIFP) develops, maintains, and coordinates all FSIS activities to prevent, prepare for, respond to, and recover from significant incidents resulting from intentional contamination or deliberate acts of

terrorism and other significant incidents affecting meat, poultry, and processed egg products. Food defense is the protection of food products from intentional contamination intended to harm public health or cause economic disruption. As part of ODIFP, the Food Defense Assessment Staff works with government agencies, industry, and other organizations to develop and implement strategies to prevent, protect against, mitigate, respond to, and recover from intentional contamination of the food supply. FSIS food defense activities are guided by national policies and directives, including Homeland Security Presidential Directive Nine, which requires USDA to perform vulnerability assessments of the food system and update these vulnerability assessments every two years.

FSIS strives to continually assess current food defense vulnerabilities, identify new food defense vulnerabilities, and remain aware of current and planned food defense research efforts. In order to help inform FSIS food defense activities and help protect against an intentional attack on the food supply, FSIS will administer a series of questionnaires to food industry and academic experts on vulnerabilities and research activities in the area of food defense for FSIS-regulated food products.

The first questionnaire will be conducted in Fiscal Year (FY) 2019, and the second and third questionnaires will be conducted in FY 2020 and FY 2021 respectively. The questionnaire will be administered to approximately 170 food industry and academic experts each fiscal year (FY 2019, FY 2020, and FY 2021).

The results from the FY 2019 questionnaire will inform FSIS's food defense activities, including vulnerability assessment efforts.

Estimate of Burden:

ESTIMATED ANNUAL REPORTING BURDEN FOR THE FY 2019 QUESTIONNAIRE

| Respondents | Number of respondents | Participation time | Burden (hours) |
|------------------------------------|-----------------------|--------------------|-------------------|
| Food industry and academic experts | 170 | 40 minutes | 113.3 |

ESTIMATED ANNUAL REPORTING BURDEN FOR THE FY 2020 QUESTIONNAIRE

| Respondents | Number of respondents | Participation time | Burden (hours) |
|------------------------------------|-----------------------|--------------------|-------------------|
| Food industry and academic experts | 170 | 40 minutes | 113.3 |

ESTIMATED ANNUAL REPORTING BURDEN FOR THE FY 2021 QUESTIONNAIRE

| Respondents | Number of respondents | Participation time | Burden (hours) |
|------------------------------------|-----------------------|--------------------|-------------------|
| Food industry and academic experts | 170 | 40 minutes | 113.3 |

Respondents: Food Industry and Academic Experts.

Estimated Number of Respondents: 510.

Estimated Number of Annual Responses per Respondent: 1. Estimated Total Burden on Respondents: 340 hours.

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Room 6065, South Building, Washington, DC 20250–3700; (202) 720–5627.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: http://www.fsis.usda.gov/federal-register.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public

meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: http://www.fsis.usda.gov/subscribe. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program
Discrimination Complaint Form, which may be accessed online at http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690-7442.

Email: program.intake@usda.gov.

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Paul Kiecker,

Acting Administrator.
[FR Doc. 2018–15461 Filed 7–18–18; 8:45 am]
BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rates

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the national average payments, the amount of money the Federal Government provides States for lunches, afterschool snacks, and breakfasts served to children participating in the National School Lunch and School Breakfast Programs; to the maximum reimbursement rates, the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products. Further adjustments are made to these rates to reflect higher costs of providing meals in Alaska, Hawaii and Puerto Rico. The payments and rates are prescribed on an annual basis each July.

DATES: These rates are effective from July 1, 2018 through June 30, 2019.

FOR FURTHER INFORMATION CONTACT:Jessica Saracino, Branch Chief, Program Monitoring and Operational Support

Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, VA 22302–1594.

SUPPLEMENTARY INFORMATION:

Background

Special Milk Program for Children—Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

National School Lunch and School Breakfast Programs—Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of

Lunch Payment Levels—Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1759(a)) provides special cash assistance payments to aid schools in providing free and reduced price lunches. The section 11 National Average Payment Factor for each reduced price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

Performanced-Based
Reimbursement—In addition to the funding mentioned above, school food authorized certified as meeting the meal pattern and nutrition standard requirements set forth in 7 CFR 210 and 220 are eligible to receive performance-based cash assistance for each reimbursable lunch served (an additional six cents per lunch available beginning October 1, 2012, and adjusted annually thereafter).

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced price and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced price, and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced price breakfasts served in schools determined to be in "severe need" because they serve a high percentage of needy children.

Adjusted Payments

The following specific section 4, section 11, and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2018 through June 30, 2019. Due to a higher cost of living, the average payments and maximum reimbursements for Alaska, Puerto Rico and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which schools receive as additional assistance for each meal served to participants under the Program. A notice announcing the value

of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Adjustments to the national average payment rates for all lunches served under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

Special Milk Program Payments

For the period July 1, 2018 through June 30, 2019, the rate of reimbursement for a half-pint of milk served to a nonneedy child in a school or institution that participates in the Special Milk Program is 20.50 cents reflecting a decrease of 0.25 cents from the School Year (SY) 2017–2018 level. This change is based on the 0.22 percent decrease in the Producer Price Index for Fluid Milk Products from May 2017 to May 2018.

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half-pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half-pints) for each half-pint served to an eligible child

National School Lunch Program Payments

Overall, payments for the National School Lunch Program and the Afterschool Snack Program either remained the same or increased from last years payments due to a 2.68 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2018 through June 30, 2019 in the Consumer Price Index for All Urban Consumers during the 12-month period May 2017 to May 2018 (from a level of 268.128 in May 2017, as previously published in the **Federal Register** to 275.307 in May 2018).

These changes are reflected below. Section 4 National Average Payment Factors—In school food authorities that served less than 60 percent free and reduced price lunches in School Year (SY) 2016–2017, the payments for meals served are: Contiguous States—paid rate—31 cents (no change from the SY 2017-2018 level), free and reduced price rate—31 cents (no change), maximum rate—39 cents (no change); Alaska—paid rate—51 cents (1 cent increase), free and reduced price rate— 51 cents (1 cent increase), maximum rate-61 cents (no change); Hawaii and Puerto Rico—paid rate—37 cents (1 cent increase), free and reduced price rate37 cents (1 cent increase), maximum rate—45 cents (no change).

In school food authorities that served 60 percent or more free and reduced price lunches in School Year 2016-2017, payments are: Contiguous States—paid rate—33 cents (no change from the SY 2017-2018 level), free and reduced price rate-33 cents (no change), maximum rate—39 cents (no change); Alaska—paid rate—53 cents (1 cent increase), free and reduced price rate—53 cents (1 cent increase), maximum rate—61 cents (no change); Hawaii and Puerto Rico—paid rate—39 cents (1 cent increase), free and reduced price rate—39 cents (1 cent increase), maximum rate—45 cents (no change).

School food authorities certified to receive the performance-based cash assistance will receive an additional 6 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—Contiguous States—free lunch—3 dollars (8 cents increase from the SY 2017–2018 level), reduced price lunch—2 dollars and 60 cents (8 cents increase); Alaska—free lunch—4 dollars and 87 cents (13 cents increase), reduced price lunch—4 dollars and 47 cents (13 cents increase); Hawaii and Puerto Rico—free lunch—3 dollars and 51 cents (9 cents increase), reduced price lunch—3 dollars and 11 cents (9 cents increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: Contiguous States—free snack—91 cents (3 cents increase from the SY 2017–2018 level), reduced price snack—45 cents (1 cent increase), paid snack—8 cents (no change); Alaska—free snack—1 dollar and 48 cents (4 cents increase), reduced price snack—74 cents (2 cents increase), paid snack—13 cents (no change); Hawaii and Puerto Rico—free snack—1 dollar and 6 cents (2 cents increase), reduced price snack—53 cents (1 cent increase), paid snack—9 cents (no change).

School Breakfast Program Payments

Overall, payments for the National School Breakfast Program either remained the same or increased from last years payments due to a 2.68 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2018 through June 30, 2019 in the Consumer Price Index for All Urban Consumers during the 12-month period May 2017 to May 2018 (from a level of 268.128 in May 2017, as previously published in the **Federal Register** to 275.307 in May 2018).

These changes are reflected below. For schools "not in severe need" the payments are: Contiguous States—free breakfast—1 dollar and 79 cents (4 cents increase from the SY 2017–2018 level), reduced price breakfast—1 dollar and 49 cents (4 cents increase), paid breakfast—31 cents (1 cent increase); Alaska—free breakfast—2 dollars and 87 cents (8 cents increase), reduced price breakfast—2 dollars and 57 cents (8 cents increase), paid breakfast—46 cents (1 cent increase); Hawaii and Puerto Rico—free breakfast—2 dollars and 9

cents (6 cents increase), reduced price breakfast—1 dollar and 79 cents (6 cents increase), paid breakfast—35 cents (1 cent increase).

For schools in "severe need" the payments are: Contiguous States—free breakfast—2 dollars and 14 cents (5 cents increase from the SY 2017-2018 level), reduced price breakfast—1 dollar and 84 cents (5 cents increase), paid breakfast—31 cents (1 cent increase): Alaska-free breakfast-3 dollars and 43 cents (8 cents increase), reduced price breakfast—3 dollars and 13 cents (8 cents increase), paid breakfast—46 cents (1 cent increase); Hawaii and Puerto Rico-free breakfast-2 dollars and 50 cents (7 cents increase), reduced price breakfast-2 dollars and 20 cents (7 cents increase), paid breakfast—35 cents (1 cent increase).

Payment Chart

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including severe need schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia, Virgin Islands, and Guam are those specified for the contiguous States.

SCHOOL PROGRAMS—MEAL, SNACK AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES [Expressed in dollars or fractions thereof, effective from: July 1, 2018–June 30, 2019]

| National school lunch program ¹ | Less than 60% | Less than 60% +6 cents ² | 60% or more | 60% or more +6 cents ² | Maximum rate | Maximum rate +6 cents ² |
|--|---------------|---|--------------|---|--------------|--|
| CONTIGUOUS STATES: | 0.01 | 0.07 | 0.00 | 0.00 | 0.00 | 0.45 |
| PAID | 0.31 2.91 | 0.37 2.97 | 0.33 2.93 | 0.39 2.99 | 0.30 3.08 | 0.45 3.14 |
| REDUCED PRICEFREE | 3.31 | 3.37 | 2.93 3.33 | 3.39 | 3.48 | 3.54 |
| ALASKA: | 0.0. | 0.07 | 0.00 | 0.00 | 00 | 0.0 . |
| PAID | 0.51 | 0.57 | 0.53 | 0.59 | 0.62 | 0.67 |
| REDUCED PRICE | 4.98 | 5.04 | 5.00 | 5.06 | 5.22 | 5.28 |
| FREE | 5.38 | 5.44 | 5.40 | 5.46 | 5.62 | 5.68 |
| HAWAII and PUERTO RICO: | | | | | | |
| PAID | 0.37 | 0.43 | 0.39 | 0.45 | 0.45 | 0.51 |
| REDUCED PRICE | 3.48 | 3.54 | 3.50 | 3.56 | 3.66 | 3.73 |
| FREE | 3.88 | 3.94 | 3.90 | 3.96 | 4.06 | 4.12 |

| School breakfast program | Non-severe need | Severe need |
|--------------------------|--------------------|-------------|
| CONTIGUOUS STATES: | | |
| PAID | 0.31 | 0.31 |
| REDUCED PRICE | 1.49 | 1.84 |
| FREE | 1.79 | 2.14 |
| ALASKA: | | |
| PAID | 0.46 | 0.46 |
| REDUCED PRICE | 2.57 | 3.13 |

| School breakfast program | Non-severe need | Severe need |
|-----------------------------|--------------------|-------------|
| FREEHAWAII and PUERTO RICO: | 2.87 | 3.43 |
| PAID | 0.35 | 0.35 |
| REDUCED PRICE | 1.79 | 2.20 |
| FREE | 2.09 | 2.50 |

| Special milk program | All milk | Paid milk | Free milk |
|--|----------|-----------|------------------------------------|
| SPECIAL PROGRAMS WITHOUT FREE OPTION PRICING PROGRAMS WITH FREE OPTION NONPRICING PROGRAMS | 0.2050 | N/A | N/A. |
| | N/A | 0.2050 | Average Cost Per 1/2 Pint of Milk. |
| | 0.2050 | N/A | N/A. |

After school snacks served in after school care programs

| CONTIGUOUS STATES: PAID REDUCED PRICE FREE | 0.08 0.45 0.91 |
|--|----------------------|
| ALASKA: PAID REDUCED PRICE FREE | 0.13 0.74 1.48 |
| HAWAII and PUERTO RICO: PAID | 0.09 0.53 1.06 |

¹ Payment listed for Free and Reduced Price Lunches include both section 4 and section 11 funds.

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This notice has been determined to be not significant and was reviewed by the Office of Management and Budget in conformance with Executive Order

National School Lunch, School Breakfast, and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553, and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

Authority: Sections 4, 8, 11, and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773(b)).

Dated: July 13, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service. [FR Doc. 2018–15465 Filed 7–18–18; 8:45 am]

BILLING CODE 3410-30-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Child and Adult Care Food Program: National Average Payment Rates, Day Care Home Food Service Payment Rates, and Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes for the Period July 1, 2018 Through June 30, 2019

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the annual adjustments to the national average payment rates for meals and snacks served in child care centers, outside-school-hours care centers, atrisk afterschool care centers, and adult day care centers; the food service payment rates for meals and snacks served in day care homes; and the administrative reimbursement rates for sponsoring organizations of day care homes, to reflect changes in the Consumer Price Index. Further adjustments are made to these rates to reflect the higher costs of providing meals in Alaska and Hawaii. The adjustments contained in this notice are made on an annual basis each July, as required by the laws and regulations governing the Child and Adult Care Food Program.

DATES: These rates are effective from July 1, 2018 through June 30, 2019.

FOR FURTHER INFORMATION CONTACT:

Jessica Saracino, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 640, Alexandria, Virginia 22302–1594.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to sections 4, 11, and 17 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753, 1759a and 1766), section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) and 7 CFR 226.4, 226.12 and 226.13 of the Program regulations, notice is hereby given of the new payment rates for institutions participating in the Child and Adult Care Food Program (CACFP). As provided for under the law, all rates in the CACFP must be revised annually, on July 1, to reflect changes in the Consumer Price Index (CPI), published by the Bureau of Labor Statistics of the United States Department of Labor, for the most recent 12-month period. These rates are in effect during the period July 1, 2018 through June 30, 2019.

Adjusted Payments

The following national average payment factors and food service payment rates for meals and snacks are in effect from July 1, 2018 through June

² Performance-based cash reimbursement (adjusted annually for inflation).

30, 2019. All amounts are expressed in dollars or fractions thereof. Due to a higher cost of living, the reimbursements for Alaska and Hawaii are higher than those for all other States. The District of Columbia, Virgin Islands, Puerto Rico, and Guam use the figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each lunch or supper served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the Federal Register.

Adjustments to the national average payment rates for all meals served under the Child and Adult Care Food Program are rounded down to the nearest whole cent.

National Average Payment Rates for Centers

The changes in the national average payment rates for centers reflect a 2.68 percent increase during the 12-month period from May 2017 to May 2018 (from 268.128 in May 2017, as previously published in the **Federal Register**, to 275.307 in May 2018) in the food away from home series of the CPI for All Urban Consumers.

Payments for breakfasts served are: Contiguous States—paid rate—31 cents (1 cent increase from 2017–2018 annual level), reduced price rate—1 dollar and 49 cents (4 cents increase), free rate—1 dollar and 79 cents (4 cents increase); Alaska—paid rate—46 cents (1 cent increase), reduced price rate—2 dollars and 57 cents (8 cents increase), free rate—2 dollars and 87 cents (8 cents increase); Hawaii—paid rate—35 cents (1 cent increase), reduced price rate—1 dollar and 79 cents (6 cents increase), free rate—2 dollars and 09 cents (6 cents increase).

Payments for lunch or supper served are: *Contiguous States*—paid rate—31 cents (no change from 2017–2018 annual level), reduced price rate—2

dollars and 91 cents (8 cents increase), free rate—3 dollars and 31 cents (8 cents increase); Alaska—paid rate—51 cents (1 cent increase), reduced price rate—4 dollars and 98 cents (14 cents increase), free rate—5 dollars and 38 cents (14 cents increase); Hawaii—paid rate—37 cents (1 cent increase), reduced price rate—3 dollars and 48 cents (10 cents increase), free rate—3 dollars and 88 cents (10 cents increase).

Payments for snack served are: Contiguous States—paid rate—8 cents (no change from 2017–2018 annual level), reduced price rate—45 cents (1 cent increase), free rate—91 cents (3 cents increase); Alaska—paid rate—13 cents (no change), reduced price rate—74 cents (2 cents increase), free rate—148 cents (4 cents increase); Hawaii—paid rate—9 cents (no change), reduced price rate—53 cents (1 cent increase), free rate—1 dollar and 6 cents (2 cents increase).

Food Service Payment Rates for Day Care Homes

The changes in the food service payment rates for day care homes reflect a 0.14 percent increase during the 12-month period from May 2017 to May 2018 (from 238.964 in May 2017, as previously published in the **Federal Register**, to 239.287 in May 2018) in the food at home series of the CPI for All Urban Consumers.

Payments for breakfast served are: Contiguous States—tier I—1 dollar and 31 cents (no change from 2017–2018 annual level) and tier II—48 cents (no change); Alaska—tier I—2 dollars and 9 cents (no change) and tier II—74 cents (no change); Hawaii—tier I—1 dollar and 53 cents (1 cent increase) and tier II—55 cents (no change).

Payments for lunch and supper served are: Contiguous States—tier I—2 dollars and 46 cents (no change from 2017–2018 annual level) and tier II—1 dollar and 48 cents (no change); Alaska—tier I—3 dollars and 99 cents (no change) and tier II—2 dollars and 41 cents (1 cent increase); Hawaii—tier I—2 dollars

and 88 cents (no change) and tier II—1 dollar and 74 cents (no change).

Payments for snack served are: Contiguous States—tier I—73 cents (no change from 2017–2018 annual level) and tier II—20 cents (no change); Alaska—tier I—1 dollar and 19 cents (no change) and tier II—33 cents (1 cent increase); Hawaii—tier I—86 cents (1 cent increase) and tier II—23 cents (no change).

Administrative Reimbursement Rates for Sponsoring Organizations of Day Care Homes

The changes in the administrative reimbursement rates for sponsoring organizations of day care homes reflect a 2.80 percent increase during the 12-month period, May 2017 to May 2018 (from 244.733 in May 2017, as previously published in the **Federal Register**, to 251.588 in May 2018) in the series for all items of the CPI for All Urban Consumers.

Monthly administrative payments to sponsors for each sponsored day care home are: Contiguous States—initial 50 homes—118 dollars (4 dollar increase from 2017-2018 annual level), next 150 homes—90 dollars (3 dollar increase), next 800 homes-70 dollars (2 dollar increase), each additional home—62 dollars (2 dollar increase); Alaskainitial 50 homes—191 dollars (6 dollar increase), next 150 homes—145 dollars (4 dollar increase), next 800 homes-113 dollars (3 dollar increase), each additional home—100 dollars (3 dollar increase); *Hawaii*—initial 50 homes— 138 dollars (4 dollar increase), next 150 homes—105 dollars (3 dollar increase). next 800 homes-82 dollars (2 dollar increase), each additional home—72 dollars (2 dollar increase).

Payment Chart

The following chart illustrates the national average payment factors and food service payment rates for meals and snacks in effect from July 1, 2018 through June 30, 2019.

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)

[Per meal rates in whole or fractions of U.S. dollars, effective from July 1, 2018–June 30, 2019]

| Centers | Breakfast | Lunch and supper 1 | Supplement |
|---------------------------|-----------|--------------------|------------|
| CONTIGUOUS STATES: PAID | 0.31 | 0.31 | 0.08 |
| | 1.49 | 2.91 | 0.45 |
| | 1.79 | 3.31 | 0.91 |
| PAID REDUCED PRICE FREE | 0.46 | 0.51 | 0.13 |
| | 2.57 | 4.98 | 0.74 |
| | 2.87 | 5.38 | 1.48 |
| PAID REDUCED PRICE | 0.35 | 0.37 | 0.09 |
| | 1.79 | 3.48 | 0.53 |
| | 2.09 | 3.88 | 1.06 |

CHILD AND ADULT CARE FOOD PROGRAM (CACFP)—CONTINUED

[Per meal rates in whole or fractions of U.S. dollars, effective from July 1, 2018–June 30, 2019]

| Day asse harras | Breakfast | | Lunch and supper | | Supplement | |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Day care homes | Tier I | Tier II | Tier I | Tier II | Tier I | Tier II |
| CONTIGUOUS STATESALASKAHAWAII | 1.31 2.09 1.53 | 0.48 0.74 0.55 | 2.46 3.99 2.88 | 1.48 2.41 1.74 | 0.73 1.19 0.86 | 0.20 0.33 0.23 |
| Administrative reimbursement rates for sponsoring organizations of day care homes (per home/per month rates in U.S. dollars) | | | Initial 50 | Next 150 | Next 800 | Each additional |
| CONTIGUOUS STATES | | | 118 191 138 | 90 145 195 | 70 113 82 | 62 100 72 |

¹These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods which institutions receive as additional assistance for each CACFP lunch or supper served to participants. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has been determined to be exempt under Executive Order 12866.

CACFP is listed in the Catalog of Federal Domestic Assistance under No. 10.558 and is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 2 CFR 415.3–415.6).

This notice has been determined to be not significant and was reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

This notice imposes no new reporting or recordkeeping provisions that are subject to OMB review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3518).

Authority: Sections 4(b)(2), 11a, 17(c) and 17(f)(3)(B) of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753(b)(2), 1759a, 1766(f)(3)(B)) and section 4(b)(1)(B) of the Child Nutrition Act of 1966 (42 U.S.C. 1773(b)(1)(B)).

Dated: July 13, 2018.

Brandon Lipps,

Administrator, Food and Nutrition Service. [FR Doc. 2018–15464 Filed 7–18–18; 8:45 am]

BILLING CODE 3410-30-P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Nevada State Advisory Committee

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 (FACA) that a meeting of the Nevada Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (Pacific Time) Thursday, July 26, 2018, the purpose of the meeting is for the Committee to continue planning for August 9, 2018 briefing on policing practices in Nevada.

DATES: The meeting will be held on Thursday, July 26, 2018, at 1:00 p.m. PT.

Public Call Information: Dial: 877–260–1479. Conference ID: 1176006.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@ usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 877-260-1479, conference ID number: 1176006. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over landline connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period

at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894-0508, or emailed Ana Victoria Fortes at afortes@ usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (213) 894-3437.

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=261. Please click 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 website, http:// www.usccr.gov, or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome

II. Approval Minutes From June 21, 2108 Meeting

III. Update on Speakers

IV. Vote on Flyer

V. Publicity

VI. Discuss Logistics

VII. Public Comment

VIII. Adjournment

Dated: July 15, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit. [FR Doc. 2018-15406 Filed 7-18-18; 8:45 am] BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 180608532-8537-01]

Soliciting Feedback From Users on 2020 Census Data Products

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice and Request for

Comment.

SUMMARY: Since 1790, a census of the U.S. population has been conducted every 10 years, as required by the U.S. Constitution. Following the completion of the 2020 Census, the Bureau of the Census (Census Bureau) will disseminate several data products, such as including summary and detailed data tables, national and state demographic profiles, and topical briefs. The Census Bureau anticipates publishing the plans for 2020 Census data products in a future notice and seeks information on how products for prior decennial censuses were used to help determine which products to disseminate for the 2020 Census. An upcoming live question-and-answer webinar will provide an opportunity to ask any procedural questions about how to respond to this Notice.

DATES: Comments on this notice must be received by September 17, 2018.

ADDRESSES: Please address all written comments to Karen Battle, Chief, Population Division, U.S. Census Bureau, 4600 Silver Hill Road, Room 6H174, Washington, DC 20233, or by email at POP.2020.DataProducts@ census.gov.

You may also submit comments, identified by the following Census Bureau Docket Identification Number USBC-2018-0009, to the Federal e-Rulemaking Portal: http:// www.regulations.gov. All comments received are part of the public record. No comments will be posted to http:// www.regulations.gov for public viewing until after the comment period has closed. Comments will generally be posted without change. All Personally Identifiable Information (for example, name and address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected

information. You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Karen Battle, U.S. Census Bureau, 4600 Silver Hill Road, Room 6H174,

Washington, DC 20233 or by email at POP.2020.DataProducts@census.gov.

SUPPLEMENTARY INFORMATION: The Census Bureau is conducting a comprehensive review of the decennial census data products in preparation for the 2020 Census. It seeks feedback via this Federal Register notice to understand how the public uses decennial census data products. Given the need for improved confidentiality protection, we may reduce the amount of detailed data that we release to the public. Public feedback is essential for a complete review of the decennial census data products will assist the Census Bureau in prioritizing products for the 2020 Census. The Census Bureau is not seeking feedback on apportionment counts and redistricting data products, which are constitutionally mandated.

The Census Bureau invites the public to participate in a live question-andanswer webinar on July 31, 2018 at 2:00 p.m. Eastern Daylight Time, to learn more about the feedback process. The webinar will be recorded and made available later at https:// www.census.gov/. Please note that the webinar is intended only to answer questions about the feedback process. All comments must be submitted though either electronic mail, postal mail, or the Federal e-Rulemaking portal as outlined above.

The Census Bureau released a suite of data products following the 2010 Census, including summary and detailed data tables, national and state demographic profiles, and topical briefs. See https://www.census.gov/population/ www/cen2010/glance/ for a complete listing of 2020 Census data products and table shells, all of which also are available on the American FactFinder (AFF) website, http:// factfinder.census.gov. In addition to general comments, the Census Bureau seeks feedback on the following data products:

Summary File 1 includes detailed tables on age, sex, households, families, relationship to householder, housing units, detailed race and Hispanic or Latino origin groups, and group quarters. Some tables are repeated for nine race and Hispanic or Latino origin groups.

Summary File 2 includes detailed tables on age, sex, households, families, relationship to householder, housing units, and group quarters. Most tables are shown down to the census tract level. Tables are repeated by 75 major race groups, 114 American Indian and Alaska Native (AIAN) groups, 47 Asian groups, 43 Native Hawaiian and Other Pacific Islander groups, and 51 Hispanic or Latino origin groups.

The American Indian and Alaska Native Summary File is a national-level file showing the same content as Summary File 2. Tables are repeated for the total population, the total AIAN population, and for numerous AIAN tribes. Data are shown down to the tract

The Demographic Profile shows data for age, sex, race, Hispanic or Latino origin, household relationship, household type, group quarters population, housing occupancy, and housing tenure. The Demographic Profile was released as individual profiles for each of the 50 states, the District of Columbia, and Puerto Rico down to the place/functioning minor civil divisions, as well as for the U.S., regions, divisions, and other areas that cross state boundaries.

The Summary Population and Housing Characteristics Report Series contains tables on age, sex, race, Hispanic or Latino origin, households, families, housing tenure and occupancy, population density, and area measurements. The lowest level of geography is the place level. There is a report produced for each state, the District of Columbia, Puerto Rico, and a U.S. summary.

The Population and Housing Unit Counts Report Series provides tables containing population and housing counts from the 2010 Census and selected historical censuses. Some tables also include area measurements and density. The lowest level of geography is the place level. There is a report produced for each state, the District of Columbia, Puerto Rico, and a U.S. summary. Maps are included at the end of each report, and the User Notes section in each state report documents geographic changes over the past decade.

The Census Population and Housing Tables cover a wide variety of topics, such as race, Hispanic or Latino origin, group quarters, and other data topics obtained from the 2010 Census.

Census Briefs cover a variety of topics, such as race, Hispanic or Latino origin, and age and include analysis of topics using graphs and tables.

The Census Bureau is especially interested in receiving responses to the following questions:

- 1. How are the data from each individual table and data product used? Include any specific legal, statutory, or programmatic uses. Please cite any supporting federal laws or regulations.
- 2. Why are decennial census statistics used for this purpose? Please provide a clear justification.
- 3. Without decennial census data, how would this activity be accomplished (e.g., other data sources)?
- 4. Who are the users of the specific table or data product?
- 5. Who is affected by the use of the data in this specific table or data product?
- 6. How much funding is distributed based on these data?
- 7. What is the lowest level of geography (e.g., county, census block, etc.) at which data need to be published for each specific table? Please explain why data are needed at this level of geography. The Standard Hierarchy of Census Geographic Entities can be found here: https://www2.census.gov/geo/pdfs/reference/geodiagram.pdf. The Hierarchy of American Indian, Alaska Native, and Hawaiian Areas can be found here: https://www2.census.gov/geo/pdfs/reference/aianhh diag.pdf.
- 8. In what additional levels of geography (e.g., county subdivision, school district, etc.) or geographic components (e.g., urban, rural, etc.) do data need to be published for each specific table? If the level of geography specified in the response to item seven relates to the use planned for the levels of geography requested in this response, please explain how they are related. A listing of the available geographic components can be found in the 2010 Census Summary File 1 technical documentation, Chapter 6, pages 177-180: https://www.census.gov/prod/ cen2010/doc/sf1.pdf.
- 9. What programmatic, statutory, or legal uses are there for decennial census data that are not being met by the current suite of decennial census products? The Questions Planned for the 2020 Census and American Community Survey can be found here: https://www2.census.gov/library/publications/decennial/2020/operations/planned-questions-2020-acs.pdf.

A downloadable spreadsheet contains a listing of the data products and specific tables as well as space for feedback: https://www2.census.gov/about/policies/2020-Census-Data-Products-Feedback-Spreadsheet.xlsx. This spreadsheet may be a helpful tool for respondents to provide the requested information, but its use is not required.

Paperwork Reduction Act

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current, valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 United States Code, Chapter 35, the OMB Control Number for this collection is 0690–0030.

Dated: July 13, 2018.

Ron S. Jarmin,

Associate Director for Economic Programs Performing the Non-Exclusive Functions and Duties of the Director Bureau of the Census. [FR Doc. 2018–15458 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

International Trade Administration

Corporation for Travel Promotion Board of Directors

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an opportunity for travel and tourism industry leaders to apply for membership on the Board of Directors of the Corporation for Travel Promotion.

SUMMARY: The Department of Commerce is currently seeking applications from travel and tourism leaders from specific industries for membership on the Board of Directors (Board) of the Corporation for Travel Promotion (doing business as Brand USA). The purpose of the Board is to guide the Corporation for Travel Promotion on matters relating to the promotion of the United States as a travel destination and communication of travel facilitation issues, among other

DATES: All applications must be received by the National Travel and Tourism Office by close of business on Friday, August 17, 2018.

ADDRESSES: Please submit application information by email to *CTPBoard@trade.gov*.

FOR FURTHER INFORMATION CONTACT: Julie Heizer, National Travel and Tourism Office, U.S. Department of Commerce, 1401 Constitution Avenue NW, MS10003, Washington, DC 20230; telephone: 202–482–0140; email: CTPBoard@trade.gov.

SUPPLEMENTARY INFORMATION: The Travel Promotion Act of 2009 (TPA) was signed into law on March 4, 2010, and was amended in July 2010 and December 2014. The TPA established the Corporation for Travel Promotion (the Corporation), as a non-profit corporation charged with the development and execution of a plan to (A) provide useful information to those interested in traveling to the United States; (B) identify and address perceptions regarding U.S. entry policies; (C) maximize economic and diplomatic benefits of travel to the United States through the use of various promotional tools; (D) ensure that international travel benefits all States and the District of Columbia, and (E) identify opportunities to promote tourism to rural and urban areas equally, including areas not traditionally visited by international travelers.

The Corporation is governed by a Board of Directors, consisting of 11 members with knowledge of international travel promotion or marketing, broadly representing various regions of the United States. The TPA directs the Secretary of Commerce (after consultation with the Secretary of Homeland Security and the Secretary of State) to appoint the Board of Directors for the Corporation.

At this time, the Department will be selecting four individuals with the appropriate expertise and experience from specific sectors of the travel and tourism industry to serve on the Board as follows:

(A) 1 shall have appropriate expertise and experience in the hotel accommodations sector;

(B) 1 shall have appropriate expertise and experience as officials of a city convention and visitors' bureau;

(C) 1 shall have appropriate expertise and experience in the restaurant sector;

(D) 1 shall have appropriate expertise and experience as officials of a state tourism office.

To be eligible for Board membership, individuals must have international travel and tourism marketing experience, be a current or former chief executive officer, chief financial officer, or chief marketing officer or have held an equivalent management position. Additional consideration will be given to individuals who have experience working in U.S. multinational entities with marketing budgets, and/or who are audit committee financial experts as defined by the Securities and Exchange Commission (in accordance with 15 U.S.C. 7265). Individuals must be U.S. citizens, and in addition, cannot be

federally registered lobbyists or registered as a foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Those selected for the Board must be able to meet the time and effort commitments of the Board.

Board members serve at the discretion of the Secretary of Commerce (who may remove any member of the Board for good cause). The terms of office of each member of the Board appointed by the Secretary shall be three (3) years. Board members can serve a maximum of two consecutive full three-year terms. Board members are not considered Federal government employees by virtue of their service as a member of the Board and will receive no compensation from the Federal government for their participation in Board activities. Members participating in Board meetings and events may be paid actual travel expenses and per diem by the Corporation when away from their usual places of residence.

Individuals who want to be considered for appointment to the Board should submit the following information by the Friday, August 17, 2018 deadline to the address listed in the ADDRESSES section above:

- 1. Name, title, and personal resume of the individual requesting consideration, including address, email address and phone number.
- 2. A brief statement of why the person should be considered for appointment to the Board. This statement should also address the individual's relevant international travel and tourism marketing experience and audit committee financial expertise, if any, and indicate clearly the sector or sectors enumerated above in which the individual has the requisite expertise and experience. Individuals who have the requisite expertise and experience in more than one sector can be appointed for only one of those sectors. Appointments of members to the Board will be made by the Secretary of Commerce.
- 3. An affirmative statement that the applicant is a U.S. citizen and further, is not required to register as a foreign agent under the Foreign Agents Registration Act of 1938, as amended.

Dated: July 13, 2018.

Brian Beall,

Deputy Director, National Travel and Tourism Office.

[FR Doc. 2018-15408 Filed 7-18-18; 8:45 am]

BILLING CODE 3510-DR-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-489-823]

Welded Line Pipe From the Republic of Turkey: Final Results of Countervailing Duty Administrative Review; 2015

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Borusan Istikbal Ticaret and Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (collectively, Borusan), an exporter/producer of welded line pipe from the Republic of Turkey (Turkey), received countervailable subsidies during the period of review (POR) March 20, 2015, through December 31, 2015.

DATES: Applicable July 19, 2018.

FOR FURTHER INFORMATION CONTACT:

Whitley Herndon and Andrew Medley, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: 202–482–6274 and 202–482–4987, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** on January 10, 2018. We invited interested parties to comment on the *Preliminary Results*. On January 23, 2018, Commerce exercised its discretion to toll all deadlines affected by the closure of the Federal Government from January 20 through 22, 2018. On February 12, 2018, we received timely case briefs from the Government of Turkey and from Borusan. On May 2, 2018, Commerce postponed the final results of review until July 12, 2018.

Scope of the Order

The merchandise covered by the order is welded line pipe, which is carbon and alloy steel pipe of a kind used for oil or gas pipelines, not more than 24 inches in nominal outside diameter. A full description of the scope of the order is contained in the Issues and Decision Memorandum, which is hereby adopted by this notice.⁴

Analysis of Comments Received

All issues raised in interested parties' briefs are addressed in the Issues and Decision Memorandum accompanying this notice. A list of the issues raised by interested parties and to which we responded in the Issues and Decision Memorandum is provided in the 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 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 at http:// enforcement.trade.gov/frn/. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

We made no changes to our subsidy rate calculation.

Methodology

Commerce 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 to be countervailable, we find that there is a subsidy, *i.e.*, a financial contribution from a government or public entity that gives rise to a benefit to the recipient, and that the subsidy is specific.⁵ For a full description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with section 777A(e) of the Act and 19 CFR 351.221(b)(5), we determine the total net countervailable subsidy rate for the period January 1, 2015, to December 31, 2015, to be:

¹ See Welded Line Pipe from the Republic of Turkey: Preliminary Results of Countervailing Duty Administrative Review; 2015, 83 FR 1237 (January 10, 2018) (Preliminary Results), and accompanying Preliminary Decision Memorandum (PDM).

² See Memorandum, "Deadlines Affected by the Shutdown of the Federal Government," dated January 23, 2018. All deadlines in this segment of the proceeding have been extended by three days.

³ See Memorandum, "Welded Line Pipe from Turkey: Extension of Deadline for the Final Results of 2015 Countervailing Duty Administrative Review," dated May 2, 2018.

⁴ See Memorandum, "Decision Memorandum for the Final Results of 2015 Countervailing Duty Administrative Review: Welded Line Pipe from Turkey," dated concurrently with this notice (Issues and Decision Memorandum).

⁵ 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(5A) of the Act regarding specificity.

| Company | Subsidy rate (percent) | |
|---|------------------------|--|
| Borusan Istikbal Ticaret and Borusan Mannesmann Boru Sanayi ve Ticaret A.S. ⁶ . | 0.78 ad valorem. | |

Assessment Rates

In accordance with 19 CFR 351.212(b)(2), Commerce intends to issue appropriate instructions to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of the final results of this review. Commerce will instruct CBP to liquidate shipments of subject merchandise produced and/or exported by the company listed above, entered, or withdrawn from warehouse, for consumption, from March 20, 2015, through December 31, 2015, at the *ad valorem* rate listed above.

Cash Deposit Requirements

Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown above for Borusan, 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 firms, Commerce will instruct CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company, as appropriate. Accordingly, the cash deposit requirements that will be applied to companies covered by this order, but not examined in this administrative 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 Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply

with the regulations and terms of an APO is a sanctionable violation.

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: July 12, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Scope of the Order

IV. Subsidies Valuation

A. Allocation Period

B. Attribution of Subsides

C. Benchmark Interest Rates

V. Programs Determined To Be Countervailable

VI. Programs Determined Not To Be Used During the POR

VII. Analysis of Comments

Comment 1: Treatment of the Investment Encouragement Program (IEP): Customs and Value Added Tax (VAT) Exemption Program

Comment 2: Whether To Include Borusan's Exchange Variation Income in the Total Value of Sales and Total Value of Export Sales

VIII. Recommendation

[FR Doc. 2018–15435 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-520-807]

Circular Welded Carbon-Quality Steel Pipe From the United Arab Emirates: Notice of Court Decision Not in Harmony With Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On July 9, 2018, the United States Court of International Trade (the Court) entered final judgment sustaining the final results of the remand redetermination by the Department of Commerce (Commerce) pertaining to the antidumping duty (AD) investigation of circular welded carbon-quality steel pipe (CWP) from the United Arab Emirates (UAE). Commerce is notifying the public that the final judgment in this case is not in harmony with Commerce's final determination in the AD investigation of CWP from the UAE.

DATES: Applicable July 19, 2018.
FOR FURTHER INFORMATION CONTACT:
Blaine Wiltse and Whitley Herndon,
AD/CVD Operations, Office II,
Enforcement and Compliance,
International Trade Administration,
U.S. Department of Commerce, 1401
Constitution Avenue NW, Washington,
DC 20230; telephone: (202) 482–6345
and (202) 482–6274, respectively.

SUPPLEMENTARY INFORMATION:

Background

Subsequent to the October 28, 2016, publication of the Final Determination,1 and the December 16, 2016, publication of the Order,2 Wheatland Tube Company (i.e., the petitioner), filed a complaint with the Court challenging Commerce's treatment of the cost of "caps" used by Universal Tube and Plastic Industries, LLC—Jebel Ali Branch (UTP-JA), a producer/exporter of the mandatory respondent, Universal.³ On April 24, 2018, the Court remanded Commerce's final determination with the instruction that Commerce reexamine whether UTP-JA's cost of caps should be treated as packing expenses in light of its prior treatment of this material.4

On June 22, 2018, Commerce issued its final results of redetermination, in which we reclassified UTP–JA's cost of caps as packing expenses; this revision did not change the final dumping margin for Universal.⁵ On July 9, 2018, the Court sustained the Remand Redetermination.

Timken Notice

In its decision in *Timken*,⁶ as clarified by *Diamond Sawblades*,⁷ the United States Court of Appeals for the Federal

⁶ For the Borusan Companies, we initiated on the following: Borusan Istikbal Ticaret (Istikbal) and Borusan Mannesmann Boru Sanayi ve Ticaret A.S. (BMB). As explained in the PDM, we found Istikbal and BMB to be cross-owned under Borusan Holding, A.S. No party has provided argument to the contrary; thus, for these final results, we continue to find all three companies to be cross-owned, though only BMB received countervailable subsidies in this review period.

¹ See Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates: Final Determination of Sales at Less Than Fair Value, 81 FR 75030 (October 28, 2016) (Final Determination).

² See Circular Welded Carbon-Quality Steel Pipe from the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Orders, 81 FR 91906 (December 19, 2016) (Order).

³ Universal is the name collectively used for the following group of affiliated producers/exporters of CWP: KHK Scaffolding and Framework LLC; Universal Tube and Pipe Industries, Ltd; and UTP–JA.

⁴ See Wheatland Tube Company v. United States, Court No. 17–00021, Slip Op. 18–49 (CIT April 24, 2018).

⁵ See Final Results of Redetermination Pursuant to Court Remand, Wheatland Tube Company v. United States, Court No. 17–00021, Slip Op. 18–49 (CIT April 24, 2018), dated June 21, 2018, available at: https://enforcement.trade.gov/remands/index.html (Remand Redetermination).

⁶ See Timken Co. v. United States, 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

⁷ See Diamond Sawblades Mfrs. Coalition v. United States, 626 F.3d 1374 (Fed. Cir. 2010) (Diamond Sawblades).

Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of a court decision that is not "in harmony" with a Commerce determination and must suspend liquidation of entries pending a "conclusive" court decision. The Court's July 9, 2018, final judgment sustaining Commerce's Remand Redetermination constitutes a final decision of the Court that is not in harmony with Commerce's Final Determination. This notice is published in fulfillment of the publication requirements of Timken. Accordingly, Commerce will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal, or if appealed, pending a final and conclusive court decision.

We have not amended the Final Determination because reclassifying UTP–JA's cost of caps as packing expenses did not result in a change to the weighted-average dumping margin calculated for Universal in the Final Determination, which remains 5.58 percent.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c)(1) and (e), and 777(i)(1) of the Act.

Dated: July 13, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–15566 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration [C-570-048]

Certain Carbon and Alloy Steel Cut-to-Length Plate From the People's Republic of China: Final Results of Countervailing Duty Expedited Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) has completed its expedited review of the countervailing duty (CVD) order on certain carbon and alloy steel cut-to-length plate (CTL plate) from the People's Republic of China (China) and finds that Jiangsu Tiangong Tools Company Limited (TG Tools) received countervailable subsidies during period of review (POR) January 1, 2015, through December 31, 2015.

DATES: Applicable July 19, 2018. FOR FURTHER INFORMATION CONTACT:

Ryan Mullen, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5260.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the *Preliminary Results* of this expedited review on March 21, 2018.¹ A summary of the events that occurred since we published the *Preliminary Results*, as well as a full discussion of the issues raised by parties for the final results, may be found in the Issues and Decision Memorandum² issued concurrently with, and hereby adopted by, 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 is available to all parties 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 at http://enforcement.trade.gov/frn/. The signed Issues and Decision Memorandum and the electronic version are identical in content.

Scope of the Order

The product covered by this order is CTL plate. A full description of the scope of the order is contained in the Issues and Decision Memorandum.³

Methodology

Commerce conducted this CVD expedited review in accordance with 19 CFR 351.214(k). For a full description of the methodology underlying our conclusions, see the Issues and Decision Memorandum. The subsidy programs under review, and the issues raised in the case and rebuttal briefs submitted by the parties, are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached as an Appendix to this notice.

Based on our review and analysis of the comments received from parties, we made certain changes to TG Tools' subsidy rate calculations since the *Preliminary Results*. For a discussion of these changes, *see* the Issues and Decision Memorandum and the Final Calculation Memorandum.⁴

Final Results of the Expedited Review

As a result of this expedited review, we determine the countervailable subsidy rate to be:

| Company | | |
|--|---------------|--|
| Jiangsu Tiangong Tools Company Limited, Tiangong Aihe Company Limited, Jiangsu Tiangong Group Company Limited, Jiangsu Tiangong Mould Steel R&D Center Company Limited | 26.90 percent | |

Cash Deposit Instructions

Pursuant to section 19 CFR 351.214(k)(3)(iii), the final results of this expedited review will not be the basis for the assessment of countervailing duties. Upon the issuance of these final results, Commerce will instruct Customs and Border Protection (CBP) to collect cash deposits of estimated countervailing duties for the companies subject to this expedited review, at the rates 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 expedited review. These cash deposit requirements, when imposed, shall remain in effect until further notice.

¹ See Certain Carbon and Alloy Steel Cut-to-Length Plate from the People's Republic of China: Preliminary Results of Countervailing Duty Expedited Review, 83 FR 12337 (March 21, 2018) (Preliminary Results).

² See Memorandum, "Issues and Decision Memorandum for the Final Results of Expedited Review of the Countervailing Duty Order on Certain Carbon and Alloy Steel Cut-to-Length Plate from the People's Republic of China," dated concurrently

with, and hereby adopted by, this notice (Issues and Decision Memorandum).

³ *Id*.

 $^{^4}$ Id; see also Memorandum, "Final Results Calculations for TG Tools" (June 13, 2018).

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with 19 CFR 351.214(k).

Dated: July 13, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Scope of the Order

IV. Subsidies Valuation

V. Use of Facts Otherwise Available and

Adverse Inferences

VI. Analysis of Programs

VII. Analysis of Comments

Comment 1: TG Tools' Ministerial Error Allegation

Comment 2: AFA for Land Use for LTAR Comment 3: Cross-Ownership Standard for TG Tools

Comment 4: Electricity for LTAR Calculation

Comment 5: Ocean Freight Benchmark Comment 6: VAT in Benchmarks

Comment 7: Policy Loan Calculations Comment 8: Import Tariff and VAT Exemptions Calculation

VIII. Recommendation

[FR Doc. 2018–15436 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments/modifications.

SUMMARY: Notice is hereby given that permits or permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone: (301) 427–8401; fax: (301) 713–0376.

FOR FURTHER INFORMATION CONTACT:

Shasta McClenahan (Permit Nos. 17845–03, 21238, 21348, and 21371), Carrie Hubard (Permit No. 22049), and Erin Markin (Permit No. 19496–01); at (301) 427–8401.

SUPPLEMENTARY INFORMATION: Notices were published in the Federal Register on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the Federal Register notice that announced our receipt of the application and a complete description of the research, go to www.federalregister.gov and search on the permit number provided in the table below.

| Permit No. | RIN | Applicant | Previous Federal Register Notice | Permit or amendment issuance date |
|------------|------------|--|--|-----------------------------------|
| 17845–03 | 0648-XC599 | Rachel Cartwright, Ph.D., Keiki Kohola Project, 4945 Coral Way, Oxnard, CA 93035. | 82 FR 11180; February 21, 2017. | June 14, 2018. |
| 19496–01 | 0648-XG038 | Mariana Fuentes, Ph.D., Florida State University, 3263 Foley Drive, Tallahassee, FL 32309. | 83 FR 10686; March 12, 2018 | June 5, 2018. |
| 21238 | 0648-XG028 | Center for Whale Research (Responsible Party: Kenneth Balcomb III), 355 Smuggler's Cove Road, Friday Harbor, WA 98250. | 83 FR 8435; February 27, 2018. | June 4, 2018. |
| 21348 | 0648-XG027 | NMFS Northwest Fisheries Science Center (NWFSC), 2725 Montlake Boulevard East, Seattle, WA 98112. | 83 FR 11733; March 16, 2018 | June 5, 2018. |
| 21371 | 0648-XF968 | NMFS Northeast Fisheries Science Center (NEFSC), 166 Water Street, Woods Hole, MA 02543. | 83 FR 5614; February 8, 2018 | June 4, 2018. |
| 22049 | 0648–XG206 | Living Planet Productions/Silverback Films (Responsible Party: Sarah Wade), 1 St. Augustine Yard, Gaunts Lane, Bristol, BS1 5DE, UK. | 83 FR 19710; May 4, 2018 | June 7, 2018. |

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) Were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and

policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 et seq.), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: July 16, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018-15460 Filed 7-18-18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG342

New England Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Research Steering Committee to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, August 8, 2018 at 9:30 a.m. **ADDRESSES:**

Meeting address: The meeting will be held at the Hilton Garden Inn, 100 High Street, Portsmouth, NH 03801; telephone: (603) 431–1499.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT:

Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Research Steering Committee will develop Council recommendations regarding the Research Review Policy and the purpose and functions of the RSC. They will also receive updates on improving the functionality of how research priorities are listed, Council Coordination Committee discussion, and other developments; develop any additional Council recommendations. The Committee will meet the NEFSC new Fishery Monitoring & Research Division Chief and receive updates on cooperative research activities; develop Council recommendations as well as receive an overview of the NEFMC's ongoing review of the Research-Set-Aside programs; develop Council recommendations. The Research Steering Committee will review completed research project on: An experimental fishery for silver hake/ whiting in Small Mesh Area I and the Western Raised Footrope Exemption Area; develop Council recommendations. Address other business as necessary.

Although non-emergency issues not contained on this agenda may come before the Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after the publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date. This meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

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

Dated: July 16, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15454 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG347

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a one day meeting of its Standing, Reef Fish, Mackerel and Shrimp Scientific and Statistical Committees (SSC).

DATES: The meeting will convene on Thursday, August 2, 2017, 8 a.m. to 5:30 p.m. EDT.

ADDRESSES: The meeting will be held at the Hilton Tampa Airport Westshore Hotel, located at 2225 N Lois Avenue, Tampa, FL 33607; telephone: (813) 877–6688.

Council address: Gulf of Mexico Fishery Management Council, 4701 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630. FOR FURTHER INFORMATION CONTACT: Dr. John Froeschke, Fishery Biologist, Gulf of Mexico Fishery Management Council; *john.froeschke@gulfcouncil.org*, telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Thursday, August 2, 2018: 8 a.m.-5:30 p.m.

- I. Introductions and Adoption of Agenda
- II. Approval of May 31–June 1, 2018 SSC Minutes
- III. Selection of SSC representative at August 20–23, 2018 Council meeting in Corpus Christi, TX

Standing and Mackerel SSC Session

- IV. Options Paper—Modifications to Gulf of Mexico Migratory Group Cobia Size and Possession Limits
 - a. Updated catch-per-unit effort indices for Gulf cobia
 - b. Review of draft options paper

Standing, Reef Fish and Shrimp SSC Session

V. Update on Council Request regarding shrimp effort threshold reduction in the area monitored for juvenile red snapper bycatch

Standing and Reef Fish SSC Session

- VI. Review of Procedure for Red Grouper Interim Analysis
- VII. Overview of revised SEDAR process: Research, operational, and interim tacks
- VIII. Council staff proposed modifications to the SEDAR process
- IX. Determine need for a red snapper research track assessment in 2020, followed by an operational assessment in 2021
- X. Selection of Workgroup Appointees for SEDAR 64—Yellowtail Snapper Benchmark Assessment
- XI. Specify the TORs for the 2020 operational assessments for gag and greater amberjack
- XII. Review of Gray Snapper Global SPR Analysis
- XIII. Draft Reef Fish Amendment 48/Red Drum Amendment 5
 - a. Review of revised reference sheet
 - b. Action 1–MSY proxies issues and alternatives
 - i. Summary of MSY Proxies Working Group meeting
 - ii. Revised MSY proxies alternatives
 - c. Action 4–OY alternatives
 - i. Draft OY buffer spreadsheet
 - d. Actions 2 and 3 (MSST and MFMT)
- VI. Tentative 2018/19 SSC Meeting Dates
- VII. Other Business
- -Meeting Adjourns

The meeting will be broadcast via webinar. You may register for the

webinar by visiting www.gulfcouncil.org and clicking on the SSC meeting on the calendar. https://

attendee.gotowebinar.com/register/3383291116212545537-. The Agenda is subject to change, and the latest version along with other meeting materials will be posted on www.gulfcouncil.org as they become available.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committee for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act, those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see ADDRESSES), at least 5 working days prior to the meeting.

Dated: July 16, 2018.

Tracev L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15469 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG345

Marine Mammals; File No. 21329

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that John P. Wise, Sr., Ph.D., University of Louisville, Department of Pharmacology, 500 S Preston St., Suite 1319, Louisville, KY 40202 has applied in due form for a permit to receive, import, and export biological samples from marine mammals, sea turtles, and protected sharks for scientific research purposes.

DATES: Written, telefaxed, or email comments must be received on or before August 20, 2018.

ADDRESSES: The application and related documents are available for review by selecting "Records Open for Public Comment" from the "Features" box on the Applications and Permits for Protected Species (APPS) home page, https://apps.nmfs.noaa.gov, and then selecting File No. 21329 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to NMFS.Pr1Comments@noaa.gov. Please include the File No. 21329 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Amy Hapeman, (301) 427–8401.

supplementary information: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 et seq.), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 et seq.), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 et seq.).

The applicant proposes to receive, import, and export specimens from marine mammals, sea turtles, and protected sharks under NMFS' jurisdiction to: (1) Determine concentrations of metals and other environmental contaminants in these species; and (2) establish a resource of marine mammal, sea turtle, and protected shark cell lines for use as model systems in the investigation of various factors related to the health of these protected species and as comparative tools to human studies (toxicity of metals, virology, etc.).

Import and export authority is requested worldwide and the number of animals requested per species is outlined in the take tables in the application.

No take of live wild animals would be involved; tissues would be received from the following sources: Marine mammals or sharks stranded dead or that died during rehabilitation; captive marine mammals or sharks held for public display or research; marine mammals and sharks taken in a legal fishery; marine mammals, sea turtles, or sharks sampled by other permitted researchers; and marine mammals or sharks killed during legal subsistence hunts. Once the cell lines are established, they may be transferred to other researchers for scientific research, including export to world-wide locations. The cell lines would not be sold for profit or used for commercial purposes. The requested duration of the permit is 5 years.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: July 16, 2018.

Julia Marie Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–15459 Filed 7–18–18; 8:45 am] BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG326

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting (webinar).

SUMMARY: The Groundfish Subcommittee of the Pacific Fishery Management Council's (Pacific Council's) Scientific and Statistical Committee (SSC) will hold a meeting via webinar to review a draft terms of reference for the groundfish and coastal pelagic species stock assessment review process for 2019 and 2020 and any other matters the SSC may be discussing at their upcoming September meeting in Seattle, WA. The webinar meeting is open to the public.

DATES: The SSC Groundfish Subcommittee webinar will be held Thursday, August 2, 2018, from 9 a.m. to 12 p.m. Pacific Daylight Time or until business for the day has been completed.

ADDRESSES: The SSC's Groundfish Subcommittee meeting will be held by webinar. To attend the webinar, (1) join the meeting by visiting this link https:// www.gotomeeting.com/webinar, (2) enter the webinar ID: 722-907-851, and (3) enter your name and email address (required). After logging into the webinar, please (1) dial this TOLL number: 1-415-655-0052 (not a toll-free number); (2) enter the attendee phone audio access code: 667-817-359; and (3) then enter your audio phone pin (shown after joining the webinar). Note: We have disabled mic/speakers as an option and require all participants to use a telephone or cell phone to participate. Technical Information and System Requirements: PC-based attendees are required to use Windows® 7, Vista, or XP; Mac®-based attendees are required to use Mac OS® X 10.5 or newer; Mobile attendees are required to use iPhone®, iPad®, AndroidTM phone or Android tablet (see the https:// www.gotomeeting.com/webinar/ipadiphone-android-webinar-apps). You may send an email to Mr. Kris Kleinschmidt at Kris.Kleinschmidt@ noaa.gov or contact him at (503) 820-2280, extension 411 for technical assistance. A public listening station will also be available at the Pacific Council office.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220.

FOR FURTHER INFORMATION CONTACT: Mr. John DeVore, Staff Officer, Pacific Fishery Management Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The purpose of the SSC Groundfish Subcommittee meeting is to review a draft terms of reference for the groundfish and coastal pelagic species stock assessment review process for 2019 and 2020. The review will focus on proposed changes from the National Marine Fisheries Service Northwest Fisheries Science Center. The SSC Groundfish Subcommittee may also address any other matters the SSC may

be discussing at their September meeting in Seattle, WA.

No management actions will be decided by the SSC's Groundfish Subcommittee. The SSC Groundfish Subcommittee members' role will be development of recommendations and reports for consideration by the SSC and Pacific Council at the September meeting in Seattle, WA.

Although nonemergency issues not contained in the meeting agendas may be discussed, those issues may not be the subject of formal action during these meetings. Action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent of the SSC Groundfish Subcommittee to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (503) 820–2411 at least 10 days prior to the meeting date.

Dated: July 16, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15455 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG279

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Cost Recovery Program

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

ACTION: Notification of fee percentage.

SUMMARY: NMFS publishes notification of a 1.85 percent fee for cost recovery under the Bering Sea and Aleutian Islands Crab Rationalization Program. This action is intended to provide holders of crab allocations with the fee percentage for the 2018/2019 crab fishing year so they can calculate the required payment for cost recovery fees that must be submitted by July 31, 2019.

DATES: The Crab Rationalization Program Registered Crab Receiver permit holder is responsible for submitting the fee liability payment to NMFS on or before July 31, 2019.

FOR FURTHER INFORMATION CONTACT: Kurt Iverson, (907) 586–7210.

SUPPLEMENTARY INFORMATION:

Background

NMFS Alaska Region administers the Bering Sea and Aleutian Islands Crab Rationalization Program (Program) in the North Pacific. Fishing under the Program began on August 15, 2005. Regulations implementing the Program can be found at 50 CFR part 680.

The Program is a limited access system authorized by section 313(j) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Program includes a cost recovery provision to collect fees to recover the actual costs directly related to the management, data collection, and enforcement of the Program. The Program implemented under the authority of section 313(j) is consistent with the cost recovery provisions included under section 304(d)(2)(A) of the Magnuson-Stevens Act. NMFS developed the cost recovery provision to conform to statutory requirements and to reimburse the agency for the actual costs directly related to the management, data collection, and enforcement of the Program. The cost recovery provision allows collection of 133 percent of the actual management, data collection, and enforcement costs up to 3 percent of the ex-vessel value of crab harvested under the Program. The Program provides that a proportional share of fees charged for management and enforcement be forwarded to the State of Alaska for its share of management and data collection costs for the Program. The cost recovery provision also requires the harvesting and processing sectors to each pay half the cost recovery fees. Catcher/processor quota shareholders are required to pay the full fee percentage for crab processed at sea.

A crab allocation holder generally incurs a cost recovery fee liability for every pound of crab landed. The crab allocations include Individual Fishing Quota, Crew Individual Fishing Quota, Individual Processing Quota, Community Development Quota, and the Adak community allocation. The Registered Crab Receiver (RCR) permit holder must collect the fee liability from the crab allocation holder who is landing crab. Additionally, the RCR permit holder must collect his or her own fee liability for all crab delivered to

the RCR. The RCR permit holder is responsible for submitting this payment to NMFS on or before July 31, in the year following the crab fishing year in which landings of crab were made.

The dollar amount of the fee due is determined by multiplying the fee percentage (not to exceed 3 percent) by the ex-vessel value of crab debited from the allocation. Specific details on the Program's cost recovery provision may be found in the implementing regulations at 50 CFR 680.44.

Fee Percentage

Each year, NMFS calculates and publishes in the Federal Register the fee percentage according to the factors and methodology described at § 680.44(c)(2). The formula for determining the fee percentage is the "direct program costs" divided by "value of the fishery," where "direct program costs" are the direct program costs for the Program for the previous fiscal year, and "value of the fishery" is the ex-vessel value of the catch subject to the crab cost recovery fee liability for the current year. Fee collections for any given year may be less than, or greater than, the actual costs and fishery value for that year, because, by regulation, the fee percentage is established in the first quarter of a crab fishery year based on the fishery value and the costs of the prior year.

Based upon the fee percentage formula described above, the estimated percentage of costs to value for the 2017/2018 fishery was 1.85 percent. Therefore, the fee percentage will be 1.85 percent for the 2018/2019 crab fishing year. This is an increase of 0.28 percent from the 2017/2018 fee percentage of 1.57 percent (81 FR 32329, July 13, 2017). Although direct program costs for managing the fishery increased by 2.9 percent from 2016/2017 to 2017/ 2018, the increase in the fee percentage was more affected by a \$24.0 million decrease in the value of the crab harvested under the Program. Similar to previous years, the largest direct program costs are incurred by the Alaska Department of Fish and Game and the NOAA Office of Law Enforcement.

Authority: 16 U.S.C. 1862; Pub. L. 109–241; Pub. L. 109–479.

Dated: July 16, 2018.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15468 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Sanctuary System Business Advisory Council: Public Meeting

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC). **ACTION:** Notice of open meeting.

SUMMARY: Notice is hereby given of a meeting of the Sanctuary System Business Advisory Council (council). The meeting is open to the public, and participants may provide comments at the appropriate time during the meeting. DATES: The meeting will be held Wednesday, August 22, 2018, from 9:00 a.m. to 4:30 p.m. ET, and an opportunity for public comment will be provided around 4:00 p.m. ET. Both these times and agenda topics are subject to change. ADDRESSES: The meeting will be held at JetBlue Airways Corporation, 27-01 Queens Plaza North, Long Island City, NY 11101. The meeting agenda, including times and topics, can be found here: http://sanctuaries.noaa.gov/ management/bac/meetings.html.

FOR FURTHER INFORMATION CONTACT:

LeAnn Hogan, Office of National Marine Sanctuaries, 1305 East West Highway, Silver Spring, Maryland 20910 (Phone: 240–533–0679; Fax: 301–713–0404; Email: LeAnn.Hogan@noaa.gov).

SUPPLEMENTARY INFORMATION: ONMS serves as the trustee for a network of underwater parks encompassing more than 600,000 square miles of marine and Great Lakes waters from Washington State to the Florida Keys, and from Lake Huron to American Samoa. The network includes a system of 13 national marine sanctuaries and Papahānaumokuākea and Rose Atoll marine national monuments. National marine sanctuaries protect our nation's most vital coastal and marine natural and cultural resources, and through active research, management, and public engagement, sustain healthy environments that are the foundation for thriving communities and stable economies. One of the many ways ONMS ensures public participation in the designation and management of national marine sanctuaries is through the formation of advisory councils. The Sanctuary System Business Advisory Council (council) has been formed to provide advice and recommendations to the Director regarding the relationship of ONMS with the business community. Additional information on the council

can be found at http:// sanctuaries.noaa.gov/management/ac/ welcome.html.

Matters to be Considered: The meeting will provide an opportunity for council members to hear news from across the National Marine Sanctuary System and review and comment on program initiatives. For a complete agenda, including times and topics, please visit http://sanctuaries.noaa.gov/management/bac/meetings.html. This meeting notice is being issued under Section 315 of the National Marine Sanctuaries Act, 16 U.S.C. 1445A.

Authority: 16 U.S.C. Sections 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: June 27, 2018.

John Armor,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–15452 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG361

Gulf of Mexico Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf of Mexico Fishery Management Council will hold a public hearing via webinar to solicit public comments on Amendment 13—Spiny Lobster for Management in the Gulf of Mexico.

DATES: The webinar will convene on Thursday, August 2, 2018, from 6 p.m. to 9 p.m., EDT. The webinar will begin at 6 p.m. and will conclude no later than 9 p.m.

ADDRESSES: The public hearing will be held via webinar. *Council address:* Gulf of Mexico Fishery Management Council, 4701 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Dr. Morgan Kilgour, Fishery Biologist, Gulf of Mexico Fishery Management Council; morgan.kilgour@gulfcouncil.org, telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The agenda for the following webinar is as

follows: Council staff will brief the public on the purpose and need of the amendment. The Council is currently considering aligning federal regulations in the EEZ off Florida with those of the state of Florida and creating an enhanced cooperative management procedure with Florida for federal waters off Florida. Council staff will also provide an overview of the actions and alternatives considered in the amendment including the Council preferred alternatives. Staff and a Council member will be available to answer any questions and the public will have the opportunity to provide testimony on the amendment and other related testimony. The schedule is as follows:

Tuesday, August 2, 2018; Webinar 6 p.m.—9 p.m. EST at: https://register.gotowebinar.com/register/552356550647070721.

After registering, you will receive a confirmation email containing information about joining the webinar.

—Meeting Adjourns

The public hearing will be broadcast via webinar. You may also register for the webinar by visiting www.gulfcouncil.org and clicking on the Public Hearing meeting on the calendar.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kathy Pereira at the Gulf Council Office (see ADDRESSES), at least 5 working days prior to the meeting.

Dated: July 16, 2018.

Tracey L. Thompson,

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

[FR Doc. 2018–15467 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Coral Reef Conservation Program

AGENCY: Coral Reef Conservation Program, Office for Coastal Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce

ACTION: Notice of Public Meeting, Notice of Public Comment.

SUMMARY: Notice is hereby given of a public meeting of the U.S. Coral Reef Task Force (USCRTF). Written comments must be received on or before

July 26, 2018. For specific dates, times, and locations of the public meetings, see **SUPPLEMENTARY INFORMATION**.

DATES: The meeting will be held Thursday, August 16, 2018, from 8:00 a.m. to 5:00 p.m.

ADDRESSES: You may submit comments on to the U.S. Coral Reef Task Force by any of the following methods:

Public Meeting and Oral Comments: A public meeting will be held in Pago Pago, American Samoa at the Rex H. Lee Auditorium, Highway 1, Utulei.

Written Comments: Please direct written comments to Jennifer Koss, NOAA USCRTF Steering Committee Point of Contact, NOAA Coral Reef Conservation Program, 1305 East-West Highway, N/OCRM, Silver Spring, MD 20910

FOR FURTHER INFORMATION CONTACT:

Jennifer Koss, NOAA USCRTF Steering Committee Point of Contact, NOAA Coral Reef Conservation Program, 1305 East-West Highway, N/OCRM, Silver Spring, MD 20910 at 301–533–0777 or Liza Johnson, USCRTF Executive Secretary, U.S. Department of Interior, MS–3530–MIB, 1849 C Street NW, Washington, DC 20240 at (202) 208–5004 or visit the USCRTF website at http://www.coralreef.gov.

SUPPLEMENTARY INFORMATION: The meeting provides a forum for coordinated planning and action among federal agencies, state and territorial governments, and nongovernmental partners. Registration is requested for all events associated with the meeting. This meeting has time allotted for public comment. All public comments must be submitted in written format. A written summary of the meeting will be posted on the USCRTF website within two months of occurrence. For information about the meeting, registering and submitting public comments, go to http://www.coralreef.gov.

Commenters may address the meeting, the role of the USCRTF, or general coral reef conservation issues. Before including your address, phone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment, including 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.

Established by Presidential Executive Order 13089 in 1998, the U.S. Coral Reef Task Force mission is to lead, coordinate and strengthen U.S. government actions to better preserve and protect coral reef ecosystems. Cochaired by the Departments of Commerce and Interior, Task Force members include leaders of 12 federal agencies, seven U.S. states and territories and three freely associated states.

The meeting will be held Thursday, August 16, 2018, from 8:00 a.m. to 5:00 p.m. in Pago Pago, American Samoa at the Rex H. Lee Auditorium, Highway 1, Utulei.

Nicole R. LeBoeuf,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.

[FR Doc. 2018–15453 Filed 7–18–18; 8:45 am]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG339

South Atlantic Fishery Management Council; Public Meetings

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

ACTION: Notice of public scoping meetings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold a series of public scoping meetings via webinar pertaining to three amendments to the Snapper Grouper Fishery Management Plan (FMP) for the South Atlantic Region. Amendment 47 considers modifications to the federally permitted South Atlantic snapper grouper for-hire fishery. Regulatory Amendment 29 considers options to implement best fishing practices and remove powerhead restrictions in the federal waters off the coast of South Carolina. Regulatory Amendment 32 addresses options for revisions to the inseason accountability measures for yellowtail snapper.

DATES: The scoping meetings will be held via webinar on the following dates: Amendment 47—August 6, August 9, and August 14, 2018; Regulatory Amendment 29—August 7 and August 8, 2018 and; Regulatory Amendment 32—August 15 and August 16, 2018.

ADDRESSES: The scoping meetings will be conducted via webinar.

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405. FOR FURTHER INFORMATION CONTACT: Kim Iverson, Public Information Officer, SAFMC; phone: (843) 571–4366 or toll free: (866) SAFMC–10; fax: (843) 769–4520; email: kim.iverson@safmc.net.

SUPPLEMENTARY INFORMATION: The scoping meetings will be conducted via webinar accessible via the internet from the Council's website at www.safmc.net. The scoping meetings will begin at 6 p.m. Registration for the webinars is required. Registration information will be posted on the Council's website at www.safmc.net as it becomes available.

Public scoping is the beginning phase of amendment development. The Council will gather public input and ideas on how to solve a fishery problem or address a need. The public is encouraged to identify issues, potential impacts, and reasonable solutions for options being considered in each amendment.

Amendment 47 to the Snapper Grouper FMP

Amendment 47 considers options for limiting entry into the for-hire Snapper Grouper fishery, establishing a mechanism that would allow new entrants into the for-hire Snapper Grouper fishery under limited entry, and modifying regulations that prevent anglers onboard federally permitted for-hire Snapper Grouper vessels from possessing Snapper Grouper species in state waters when harvest of these species closes in federal waters.

Regulatory Amendment 29 to the Snapper Grouper FMP

Regulatory Amendment 29 addresses the use of best fishing practices to reduce discards and discard mortality for species in the snapper grouper management complex, including: The use of venting tools and descending devices to release fish experiencing barotrauma, modification to the nonstainless-steel circle hook requirement, and specification of allowable rigs. The draft amendment also includes options to modify current regulations for the use of powerhead gear.

Regulatory Amendment 32 to the Snapper Grouper Fishery Management Plan

Regulatory Amendment 32 considers modifications to yellowtail snapper accountability measures (AM) to minimize the probability of in-season closures and consequent socioeconomic impacts.

During the scoping meetings, Council staff will present an overview of the amendment and will be available for informal discussions and to answer questions via webinar. Members of the

public will have an opportunity to go on record to record their comments for consideration by the Council. Public scoping documents and presentations for each amendment will be posted to the Council's website at http://safmc.net/safmc-meetings/ publichearings-scoping-meetings/ as they become available.

Written comments may also be submitted and must be received by 5 p.m. on August 17, 2018. The Council requests that written comments be submitted using the online public comment forms that will be posted the Council's website at http://safmc.net/safmc-meetings/public-hearings-scoping-meetings/ as they become available. Written comments may also be submitted to: Gregg Waugh, Executive Director, South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see ADDRESSES) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 16, 2018.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service. [FR Doc. 2018–15456 Filed 7–18–18; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Notice Requesting Nominations for the Advisory Committee on Commercial Remote Sensing (ACCRES)

AGENCY: National Oceanic Atmospheric Administration, Commerce.

ACTION: Request for membership nominations.

SUMMARY: The Department of Commerce is seeking highly qualified individuals who are knowledgeable about the commercial space-based remote sensing industry and uses of space-based remote sensing data to serve on the Advisory Committee on Commercial Remote Sensing (ACCRES). The Committee is comprised of leaders in the commercial space-based remote sensing industry, space-based remote sensing data users, government, and academia. The

SUPPLEMENTARY INFORMATION section of this notice provides committee and membership criteria.

FOR FURTHER INFORMATION CONTACT:

Samira Patel, Commercial Remote Sensing Regulatory Affairs Office, NOAA Satellite and Information Services, 1335 East-West Highway, Room 8247, Silver Spring, Maryland 20910; telephone (301) 713–7077, email samira.patel@noaa.gov.

SUPPLEMENTARY INFORMATION: ACCRES was established by the Secretary of Commerce on May 21, 2002, to advise the Secretary, through the Under Secretary of Commerce for Oceans and Atmosphere, on matters relating to the U.S. commercial remote sensing industry and NOAA's activities to carry out responsibilities of the Department of Commerce as set forth in 51 U.S.C. 60101, et seq.

Committee members serve in a representative capacity for a term of two years and may serve additional terms, if reappointed. No more than 20 individuals at a time may serve on the Committee. ACCRES will have a fairly balanced membership consisting of approximately 9 to 20 members. Nominations are encouraged from all interested U.S. persons and organizations representing interests affected by the regulation of remote sensing. Nominees must represent stakeholders in remote sensing, space commerce, space policy, or a related field and be able to attend committee meetings that are held usually two times per year. Membership is voluntary, and service is without pay. Each nomination that is submitted should include the proposed committee member's name and organizational affiliation, a brief description of the nominee's qualifications and interest in serving on the Committee, a curriculum vitae or resume of the nominee, and no more than three supporting letters describing the nominee's qualifications and interest in serving on the Committee. Self-nominations are acceptable. The following contact information should accompany each submission: The nominee's name, address, phone number, fax number, and email address.

Nominations should be sent to Tahara Dawkins, Director, Commercial Remote Sensing Regulatory Affairs Office, 1335 East-West Highway, G–101, Silver Spring, Maryland 20910. Nominations must be postmarked no later than 30 days from the publication date of this notice. The full text of the Committee Charter and its current membership can be viewed at the Agency's web page at:

http://www.nesdis.noaa.gov/CRSRA/accresHome.html.

Stephen M. Volz,

 $Assistant\ Administrator, for\ Satellite\ and\ Information\ Services.$

[FR Doc. 2018–14970 Filed 7–18–18; 8:45 am] BILLING CODE 3510–HR–P

COMMODITY FUTURES TRADING COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of Two Modified Systems of Records.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Commodity Futures Trading Commission (CFTC or Commission) is republishing two existing System of Record Notices (SORNs): CFTC-39, Freedom of Information Act Requests and CFTC-40, Privacy Act Requests. The modification will add three routine uses, clarify existing routine uses, and bring the SORNs in compliance with the Office of Management and Budget (OMB) Circular A-108 SORN template. Two of the new routine uses pertain to sharing information to mitigate a breach and are required by OMB Memorandum 17–12. The third new routine use is requested by the Office of Government Information Services (OGIS) to allow disclosure of personally identifiable information to OGIS for Freedom of Information Act (FOIA) dispute resolution and compliance review purposes. Other updates include identifying the specific routine uses applicable to each of the systems of records rather than relying on CFTC's previously published blanket routine uses, and administrative updates to comply with the OMB Circular A–108 SORN template format.

DATES: Comments must be received on or before August 20, 2018. This action takes effect without further notice on August 20, 2018, unless revised pursuant to comments received.

ADDRESSES: You may submit comments identified as pertaining to "Freedom of Information Act Requests" or "Privacy Act Requests" by any of the following methods:

• Agency website, via its Comments Online process: https://comments.cftc.gov. Follow the instructions for submitting comments through the website.

- *Mail:* Christopher J. 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.

Please submit your comments using only one method.

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 you believe is exempt from disclosure under the Freedom of Information Act (FOIA), a petition for confidential treatment of the exempt information may be submitted according to the procedures established 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 a submission from http://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 notice will be retained in the comment file and will be considered as required under all applicable laws, and may be accessible under the FOIA.

FOR FURTHER INFORMATION CONTACT:

Chief Privacy Officer, privacy@cftc.gov, Office of the Executive Director, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. The Privacy Act

Under the Privacy Act of 1974, 5 U.S.C. 552a, a "system of records" is defined as any group of records under the control of a Federal government agency from which information about individuals is retrieved by name or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act establishes the means by which government agencies must collect, maintain, and use information about an individual in a government system of records.

Each government agency is required to publish a notice in the **Federal Register** in which the agency identifies and describes each system of records it maintains, the reasons why the agency uses the information therein, the routine uses for which the agency will disclose such information outside the agency, and how individuals may exercise their rights under the Privacy Act.

In accordance with 5 U.S.C. 552a(r), CFTC has provided reports of these systems of records to the Office of Management and Budget (OMB) and to Congress.

II. Background

The Commodity Futures Trading Commission (CFTC or Commission) is republishing two existing SORNs: CFTC-39, Freedom of Information Act Requests and CFTC-40, Privacy Act Requests. The SORNs are being republished to add three routine uses, clarify existing routine uses, and bring the SORN in compliance with OMB Circular A–108 SORN template. The records covered under the Freedom of Information Act Requests SORN are collected and maintained to process requests made under the provisions of the FOIA, and to assist the CFTC in carrying out any other responsibilities relating to the FOIA. The records covered under the Privacy Act Requests SORN are collected and maintained to process requests made under the provisions of the Privacy Act, and to assist the CFTC in carrying out any other responsibilities relating to the Privacy Act. Two routine uses are being added to both SORNs to permit sharing with other Federal agencies or Federal entities as required by OMB Memorandum 17–12, "Preparing for and Responding to a Breach of Personally Identifiable Information." These routine uses will assist the CFTC and/or other Federal agencies or entities in responding to a suspected or confirmed breach and/or prevent, minimize, or remedy the risk of harm to the requesters, the CFTC, the Federal government, or national security. A third routine use is being added to both SORNs to permit sharing with the National Archives and Records Administration (NARA), Office of **Government Information Services** (OGIS) so OGIS can review administrative policies, procedures, and compliance, and to facilitate resolutions to disputes between persons making FOIA requests and the CFTC. Additional updates to both SORNs include clarifying the specific routine uses applicable to each system of records, and administrative updates including section name and organization updates to comply with the OMB Circular A-108 SORN template format.

III. Notice: Freedom of Information Act Requests, CFTC-39.

SYSTEM NAME AND NUMBER

Freedom of Information Act Requests, CFTC-39.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Other offices involved in the processing of requests may also maintain copies of the requests and any related internal administrative records.

SYSTEM MANAGER(S):

General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The collection of this information is authorized under the Freedom of Information Act, 5 U.S.C. 552, 5 U.S.C. 301.

PURPOSE(S) OF THE SYSTEM:

The information in this system is being collected to enable the CFTC to carry out its responsibilities under the FOIA. These responsibilities include enabling CFTC staff to receive, track, and respond to FOIA requests. This requires maintaining documentation gathered during the consideration and disposition process and administering annual reporting requirements.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals requesting information from the Commission pursuant to provisions of FOIA, 5 U.S.C. 552, and individuals who are the subjects of FOIA requests.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records includes information that may contain: requests, responsive documents, internal memoranda, electronic mail, response letters, appeals of denials, appeal determinations, electronic tracking data, fee schedules, cost calculations, and assessed cost for disclosed FOIA records.

RECORD SOURCE CATEGORIES:

Individuals requesting information from the Commission pursuant to the FOIA and CFTC staff processing the requests.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be used:

(a) To disclose information to the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures, and compliance with the Freedom of Information Act, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies;

(b) To disclose in any administrative proceeding before the Commission, in any injunctive action authorized under the Commodity Exchange Act, or in any other action or proceeding in which the Commission or its staff participates as a party or the Commission participates as amicus curiae:

(c) To disclose to Federal, State, local, territorial, Tribal, or foreign agencies for use in meeting their statutory or regulatory requirements;

(d) To disclose to contractors, grantees, volunteers, experts, students, and others performing or working on a contract, service, grant, cooperative agreement, or job for the Federal government when necessary to accomplish an agency function;

(e) To disclose to Congress upon its request, acting within the scope of its jurisdiction, pursuant to the Commodity Exchange Act, 7 U.S.C. 1 *et seq.*, and the rules and regulations promulgated thereunder;

(f) To disclose to appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records; (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm; or

(g) To disclose to another Federal agency or Federal entity, when the Commission determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or

remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The FOIA system of records stores records in this system electronically. The records are stored on the Commission's secure network and secure back-up media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information covered by this system of records notice may be retrieved by assigned control number, name of requester, or by subject of request.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records for this system will be maintained in accordance with General Records Schedule 4.2 of the National Archives and Records Administration. All approved schedules are available at http://www.cftc.gov.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical, and physical security measures. Administrative safeguards include written guidelines on handling FOIA information including agency-wide procedures for safeguarding personally identifiable information. In addition, all CFTC staff are required to take annual privacy and security training. Technical security measures within CFTC include restrictions on computer access to authorized individuals who have a legitimate need to know the information; required use of strong passwords that are frequently changed; multi-factor authentication for remote access and access to many CFTC network components; use of encryption for certain data types and transfers; firewalls and intrusion detection applications; and regular review of security procedures and best practices to enhance security. Physical safeguards include restrictions on building access to authorized individuals, 24-hour security guard service, and maintenance of records in lockable offices and filing cabinets.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act access request.

CONTESTING RECORD PROCEDURES:

Individuals contesting the content of records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.8 for full details on what to include in a Privacy Act amendment request.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act notification request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

A previous version of this SORN was published in the **Federal Register** on February 02, 2011 at 76 FR 5973.

IV. Notice: Privacy Act Requests, CFTC–40.

SYSTEM NAME AND NUMBER

Privacy Act Requests, CFTC-40.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

This system is located at the Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. Other offices involved in the processing of requests may also maintain copies of the requests and any related internal administrative records.

SYSTEM MANAGER(S):

General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The collection of this information is authorized under the Privacy Act, 5 U.S.C. 552a, 5 U.S.C. 301.

PURPOSE(S) OF THE SYSTEM:

The information in this system is being collected to enable the CFTC to carry out its responsibilities under the Privacy Act. These responsibilities include enabling CFTC staff to receive, track, and respond to Privacy Act requests.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals filing requests for access to, correction of, or an accounting of disclosures of personal information contained in systems of records maintained by the Commission, pursuant to the Privacy Act of 1974. 5 U.S.C. 552a.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests, responsive documents, internal memoranda, response letters, appeals of denials, appeal determinations, and electronic tracking data.

RECORD SOURCE CATEGORIES:

Individuals requesting information from the Commission pursuant to the Privacy Act and CFTC staff processing the requests.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be used:

- (a) To disclose information to the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures, and compliance with the Freedom of Information Act, and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies;
- (b) To disclose in any administrative proceeding before the Commission, in any injunctive action authorized under the Commodity Exchange Act, or in any other action or proceeding in which the Commission or its staff participates as a party or the Commission participates as amicus curiae;
- (c) To disclose to Federal, State, local, territorial, Tribal, or foreign agencies for use in meeting their statutory or regulatory requirements;
- (d) To disclose to anyone during the course of a Commission investigation if Commission staff has reason to believe that the person to whom it is disclosed may have further information about matters relevant to the subject of the investigation;

- (e) To disclose to contractors, grantees, volunteers, experts, students, and others performing or working on a contract, service, grant, cooperative agreement, or job for the Federal government when necessary to accomplish an agency function;
- (f) To disclose to Congress upon its request, acting within the scope of its jurisdiction, pursuant to the Commodity Exchange Act, 7 U.S.C. 1 *et seq.*, and the rules and regulations promulgated thereunder;
- (g) To disclose to appropriate agencies, entities, and persons when (1) the Commission suspects or has confirmed that there has been a breach of the system of records; (2) the Commission has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Commission (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm; or
- (h) To disclose to another Federal agency or Federal entity, when the Commission determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The Privacy Act Requests system of records stores records in this system electronically. The records are stored on the Commission's secure network, and on secure back-up media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information covered by this system of records notice may be retrieved by assigned control number, name of requester, or by subject of request.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records for this system will be maintained in accordance with General Records Schedule 4.2 of the National Archives and Records Administration. All approved schedules are available at http://www.cftc.gov.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are protected from unauthorized access and improper use through administrative, technical, and physical security measures. Administrative safeguards include agency-wide training and procedures for safeguarding personally identifiable information. Technical security measures within CFTC include restrictions on computer access to authorized individuals who have a legitimate need to know the information; required use of strong passwords that are frequently changed; multi-factor authentication for remote access and access to many CFTC network components; use of encryption for certain data types and transfers; firewalls and intrusion detection applications; and regular review of security procedures and best practices to enhance security. Physical safeguards include restrictions on building access to authorized individuals, 24-hour security guard service, and maintenance of records in lockable offices and filing cabinets.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves or seeking access to records about themselves in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in Privacy Act access request.

CONTESTING RECORD PROCEDURES:

Individuals contesting the content of records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.8 for full details on what to include in a Privacy Act amendment request.

NOTIFICATION PROCEDURES:

Individuals seeking notification of any records about themselves contained in this system of records should address written inquiries to the Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581. See 17 CFR 146.3 for full details on what to include in a Privacy Act notification request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

A previous version of this SORN was published in the **Federal Register** on February 02, 2011 at 76 FR 5973.

Issued in Washington, DC, on July 13, 2018, by the Commission.

Robert Sidman,

Deputy Secretary of the Commission. [FR Doc. 2018–15392 Filed 7–18–18; 8:45 am] BILLING CODE 6351–01–P

DEPARTMENT OF EDUCATION

[Docket ID ED-2018-FSA-0029]

Privacy Act of 1974; Matching Program

AGENCY: Department of Education. **ACTION:** Notice of a New Matching Program.

SUMMARY: This provides notice of the reestablishment of the matching program between the U.S. Department of Education (Department) and the Social Security Administration (SSA). The purpose of the matching program is to assist the Department in facilitating borrowers who owe a balance on one or more student loans under title IV of the Higher Education Act of 1965, as amended (HEA), should they wish to do so, to more efficiently and effectively apply for a total and permanent disability (TPD) discharge of their student loans. The matching program also will assist the Department in allowing recipients of Teacher Education Assistance for College and Higher Education (TEACH) Grants under title IV of the HEA who are obligated to repay due to failure to complete their agreement to serve, should they wish to do so, to more efficiently and effectively apply for a TPD discharge of their agreement to serve.

DATES: Submit your comments on the proposed matching program on or before August 20, 2018.

The matching program will go into effect 30 days after the publication of this notice, on July 19, 2018, unless comments have been received from interested members of the public requiring modification and republication of the notice. The matching program will continue for 18 months after the effective date and may be extended for an additional 12 months, if the respective Data Integrity Boards (DIBs) of the Department and SSA determine that the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal

or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- Federal eRulemaking Portal: Go to www.regulations.gov to submit your comments electronically. Information on using Regulations.gov, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the "help" tab.
- Postal Mail, Commercial Delivery, or Hand Delivery: If you mail or deliver your comments about these proposed regulations, address them to Brenda Seidel, Management and Program Analyst, Federal Student Aid, U.S. Department of Education, 830 First Street NE, Washington, DC 20202–5320, Telephone: 202–377–3982.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Pam Eliadis, Service Director, System Operations & Aid Delivery Management, Federal Student Aid, U.S. Department of Education, 830 First Street NE, Washington, DC 20202–5320. Telephone: 202–377–3554.

SUPPLEMENTARY INFORMATION: We provide this notice in accordance with Privacy Act of 1974, as amended (Privacy Act) (5 U.S.C. 552a); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100–503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular No. A–108.

Participating Agencies: The U.S. Department of Education and the Social Security Administration.

Authority For Conducting The Matching Program: The Department's legal authority to enter into this matching program and to disclose information as part of this matching program is sections 420N(c), 437(a)(1), 455(a)(1), and 464(c)(1)(F)(ii and iii) of the HEA (20 U.S.C. 1070g–2(c), 1087(a)(1), 1087e(a)(1)), and 1087dd(c)(1)(F)(ii and iii)), the regulations promulgated pursuant to these sections (34 CFR 674.61(b),

682.402(c), 685.213, and 686.42(b)), and the Privacy Act (5 U.S.C. 552a(b)(3)).

SSA's legal authority to disclose information as part of this computer matching program is section 1106 of the Social Security Act (42 U.S.C. 1306), the regulations promulgated pursuant to that section (20 CFR part 401), and the Privacy Act (5 U.S.C. 552a(b)(3)).

Purpose(s): The matching program will assist the Department in facilitating borrowers who owe a balance on one or more student loans under title IV of the HEA, should they wish to do so, to more efficiently and effectively apply for a TPD discharge of their student loans. The matching program also will assist the Department in allowing recipients of TEACH Grants under title IV of the HEA who are obligated to repay due to failure to complete their agreement to serve, should they wish to do so, to more efficiently and effectively apply for a TPD discharge of their TEACH Grant service obligations.

Categories of Individuals: The Department will disclose to SSA individually identifiable information about individual borrowers who owe a balance on one or more loans under Title IV of the HEA. The Department also will disclose to SSA individually identifiable information about TEACH grant recipients who fail to complete their agreements to serve. SSA will compare the data provided by the Department with SSA data recorded in SSA's Disability Control File (DCF) and Master Beneficiary Record (MBR).

Categories of Records: The records to be used in the matching program are described as follows:

The Department will disclose to SSA the name, date of birth (DOB), and Social Security number (SSN) of individuals who owe a balance on one or more student loans under title IV of the HEA from the system of records entitled "National Student Loan Data System (NSLDS)" (18–11–06), as last published in the **Federal Register** in full on June 28, 2013 (78 FR 38963) and as last updated on April 2, 2014 (79 FR 18534).

The data from the Department described in the preceding paragraph will be matched with SSA data recorded in the Disability Control File, which originate from the Supplemental Security Income Record and Special Veterans Benefits (SSR/SVB), 60–0103, published in the **Federal Register** on January 11, 2006 (71 FR 1830) and updated on December 10, 2007 (72 FR 69723), and the Master Beneficiary Record (MBR) SSA/ORSIS 60–0090, published in the **Federal Register** on January 11, 2006 (71 FR 1826) and updated on December 10, 2007 (72 FR

69723) and July 5, 2013 (78 FR 40542), in order to provide the Department with Medical Improvement Not Expected disability data.

System(s) of Records: The Department will disclose to SSA information from, and maintain information obtained from SSA in, the Department's system of records entitled "National Student Loan Data System (NSLDS)" (18-11-06), as last published in the Federal Register in full on June 28, 2013 (78 FR 38963) and last updated on April 2, 2014 (79 FR 18534). SSA will disclose to the Department information from SSA's "Supplemental Security Income Record and Special Veterans Benefits" system of records 60-0103, published in the Federal Register on January 11, 2006 (71 FR 1830) and updated on December 10, 2007 (72 FR 69723), and the Master Beneficiary Record system of records 60-0090, published in the Federal Register on January 11, 2006 (71 FR 1826) and updated on December 10, 2007 (72 FR 69723) and July 5, 2013 (78 FR 40542).

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (such as, braille, large print, audiotape, or compact disc) on request to Lisa Tessitore, Program Operations Specialist, Federal Student Aid, U.S. Department of Education, 830 First Street NE, Washington, DC 20202–5320. Telephone: 202–377–3249.

Electronic Access to This Document:
The official version of this document is
the document published in the Federal
Register. You may access the official
edition of the Federal Register and the
Code of Federal Regulations via the
Federal Digital System at: www.gpo.gov/
fdsys. At this site you can view this
document, as well as all other
documents of this Department
published in the Federal Register, in
text or Portable Document Format. To
use PDF you must have Adobe Acrobat
Reader, which is available free at the
site

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

James F. Manning,

Acting Chief Operating Officer, Federal Student Aid.

[FR Doc. 2018–15457 Filed 7–18–18; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ18-16-000]

Oncor Electric Delivery Company LLC; Notice of Filing

Take notice that on July 3, 2018, Oncor Electric Delivery Company LLC submitted its second revised tariff filing: Oncor TFO Tariff Rate Changes to be effective 7/1/2018.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at http://www.ferc.gov. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at http://www.ferc.gov, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the website 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.

Comment Date: 5:00 p.m. Eastern Time on July 24, 2018.

Dated: July 12, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018-15324 Filed 7-18-18; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. NJ18-15-000]

Oncor Electric Delivery Company LLC; Notice of Filing

Take notice that on July 3, 2018, Oncor Electric Delivery Company LLC submitted its tariff filing: Oncor Tex-La Tariff Rate Changes to be effective 7/1/ 2018.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at http://www.ferc.gov. Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

This filing is accessible on-line at http://www.ferc.gov, using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the website 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.

Comment Date: 5:00 p.m. Eastern Time on July 24, 2018.

Dated: July 12, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018-15323 Filed 7-18-18; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2018-0007; FRL-9980-26]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before August 20, 2018.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), email address: BPPDFRNotices@epa.gov., Anita Pease, Antimicrobials Division (AD) (7510P), email address: ADFRNotices@epa.gov. Michael Goodis, Registration Division (RD) (7505P), email address: RDFRNotices@epa.gov. The mailing address and phone number for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305–7090.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. What should I consider as I prepare my comments for EPA?

- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

New Active Ingredients

1. File Symbol: 524—ALG. Docket ID number: EPA—HQ—OPP—2018—0245. Applicant: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167. Product name: LCO Liquid Additive. Active ingredient: Plant regulator—LCO MOR116 (chemical name: D-glucose, O-6-deoxy-2-O-methyl-α-Lgalactopyranosyl-(1→6)-O-[O-2-deoxy-2-[[(11Z)-1-oxo-11-octadecen-1-yl]amino]β-D-glucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-2-(acetylamino)-2-deoxy-β-D-glucopyranosyl-(1→4)]-2-(acetylamino)-2-deoxy-; and D-glucose, O-2-deoxy-2-[[(11Z)-1-oxo-11octadecen-1-yl]amino]-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-[6-deoxy-α-Lgalactopyranosyl-(1→6)]-2-(acetylamino)-2-deoxy-) at 0.0000266%. Proposed use: Seed treatment. Contact: BPPD.

- 2. File Symbol: 524–ALU. Docket ID number: EPA-HQ-OPP-2018-0245. Applicant: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167. Product name: LCO MOR116 MP. Active ingredient: Plant regulator—LCO MOR116 (chemical name: D-glucose, O-6-deoxy-2-O-methyl-α-Lgalactopyranosyl-(1→6)-O-[O-2-deoxy-2-[[(11Z)-1-oxo-11-octadecen-1-yl]amino]β-D-glucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl- $(1\rightarrow 4)$ -2-(acetylamino)-2-deoxy-β-D-glucopyranosyl-(1→4)]-2-(acetylamino)-2-deoxy-; and D-glucose, O-2-deoxy-2-[[(11Z)-1-oxo-11octadecen-1-yl]amino]-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-2-(acetylamino)-2-deoxy-β-Dglucopyranosyl-(1→4)-O-[6-deoxy-α-Lgalactopyranosyl-(1→6)]-2-(acetylamino)-2-deoxy-) at 0.013%. Proposed use: Manufacturing-use product. Contact: BPPD.
- 3. File Symbol: 7969–UEE. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: VediraTM Cockroach Gel Bait. Active ingredient: Insecticide-Broflanilide at 0.25%. Proposed Use: To kill Asian and German cockroaches in and around commercial, institutional, and warehousing establishments [including computer facilities, food/feed processing plants, hospitals, hotels, housing and containment areas (i.e. arenas, barns, cages, hatcheries, houses, hutches, kennels, parlors, pens, sheds,

- shelters, stables) for animals (*i.e.* avian, bovine, canine, equine, feline, hircine, leporine, murine, porcine), laboratories, milk houses, motels, nursing homes, pet shops, poultry facilities (including hatchery, egg packaging, and breeding facilities), restaurants, schools, sewers, supermarkets, warehouses, and zoos], residences, and transportation equipment (aircraft—cargo areas only, boats, buses, ships, and trains). *Contact:* RD.
- 4. File Symbol: 7969–UEG. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: NurizmaTM SC Insecticide. Active ingredient: Insecticide—Broflanilide at 30%. Proposed Use: For control of soil insects in corn grown for seed, field corn, popcorn, sweet corn; and tuberous and corm vegetables, Crop Subgroup 1C. Contact: RD.
- 5. File Symbol: 7969–UEN. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: CimegraTM SC Insecticide. Active ingredient: Insecticide-Broflanilide at 10%. Proposed Use: For control of soil insects in corn grown for seed, field corn, popcorn, sweet corn; and tuberous and corm vegetables, Crop Subgroup 1C. Contact: RD.
- 6. File Symbol: (7969–EUP–UT). Applicant: BASF Corporation. Pesticide Chemical: Broflanilide. Summary of Request: The purpose of the requested EUP is to generate efficacy data on structural protection applications using conventional application equipment and the BASF Corporation-patented HP Unit to protect structures from termites. Contact: RD.
- 7. File Symbol: 7969–UER. Docket ID number: EPA-HQ-OPP-2018-0053. Applicant: BASF Corporation. Product name: Terinda™ Foam Termiticide/ Insecticide. Active ingredient: Insecticide-Broflanilide at 0.0045%. Proposed Use: To kill termites (drywood and subterranean) and foraging carpenter ants in and around apartments, homes, food/feed handling establishments (non-food/feed areas), restaurants, hospitals and nursing homes (non-patient areas), hotels and motels, hobby greenhouses, interiorscapes, mobile homes, office buildings, schools, transportation equipment (buses, cargo trucks, trailers, and trains), warehouses and other commercial and industrial buildings in addition to outdoor spot treatments. Contact: RD.
- 8. File Symbol: 7969–UEU. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: VediraTM Ant Gel Bait. Active ingredient: Insecticide-Broflanilide at 0.02%. Proposed Use: To kill ants

- (acrobat, Argentine, bigheaded, black carpenter, crazy, field, ghost, honey, little black, odorous house, pavement, rover, and thief) in and around commercial, industrial, and residential buildings including apartments, garages, food storage areas, homes, hospitals and nursing homes, hotels, motels, office buildings, restaurants and other food handling establishments, schools, supermarkets, transportation equipment (buses, boats, ships, trains, planes), utilities, and warehouses. *Contact:* RD.
- 9. File Symbol: 7969-URA. Docket ID number: EPA-HQ-OPP-2018-0053. Applicant: BASF Corporation. Product name: VediraTM Granular Ant Bait. Active ingredient: Insecticide-Broflanilide at 0.005%. Proposed Use: To kill ants (acrobat, Argentine, bigheaded, crazy, Florida carpenter, foraging fire, ghost, little black, odorous house, pavement, rover, and thief) and crickets in and around commercial buildings and other structures, food handling facilities, food processing plants, food storage areas, golf courses, homes, hotels, meat packing plants, lawns, motels, restaurants and other food handling establishments, nonoccupied patient areas of hospitals and nursing homes, parks, residential areas, schools, supermarkets, turf and warehouses. Contact: RD.
- 10. File Symbol: 7969-URG. Docket ID number: EPA-HO-OPP-2018-0053. Applicant: BASF Corporation. Product name: VediraTM Granular Fly Bait. Active ingredient: Insecticide-Broflanilide at 0.025%. Proposed Use: To kill flies (blue bottle, house, phorid, and small fruit or vinegar) in and around Commercial buildings, Industrial buildings, and Other manmade structures; Garbage or refuse bins and receptacles; or Other areas where flies may be a nuisance or health hazard Bakeries; Campgrounds; Carnivals; Circuses; Concert arenas; Confectionaries; County and state fair facilities; Dairy areas; Festival grounds, Food handling establishments; Food processing plants; Food storage areas; Food vending structures; Golf courses; Grain mills; Granaries; Hospitals; Hotels; Housing and containment areas (i.e., Arenas, Barns, Cages, Hatcheries, Houses, Hutches, Kennels, Parlors, Pens, Sheds, Shelters, Stables) for Animals (i.e., Avian, Bovine, Canine, Equine, Feline, Hircine, Leporine, Murine, Porcine); Interiorscapes; Libraries; Marinas; Meat, Poultry and egg processing facilities; Meat packing plants; Milk houses; Motels; Museums; Nursing homes; Pavilions; Research facilities; Resorts; Restaurants; Mobile food vendors; Parking ramps; Poultry facilities (including: Hatchery, Egg

packaging, Breeding facilities); Public picnic areas; Public restrooms; Recreational rest areas; Schools; Supermarkets; Temporary shelters; Theme parks; Terminals; Transportation equipment (Barges, Ships, Trailers, Trains, Trucks); Utilities; Warehouses; Waysides; Wildlife refuge areas; Zoos. Contact: RD.

11. File Symbol: 7969–URI. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: Teraxxa™ Insecticide Seed Treatment. Active ingredient: Insecticide-Broflanilide at 34.93%. Proposed/Use: Seed treatment for insect control in wheat (all types), barley, oats, rye, triticale, amaranth grain, buckwheat (all types), cañihua, chia, cram-cram, huauzontle, quinoa, and spelt. Contact: RD.

12. File Symbol: 7969-URL. Docket ID number: EPA-HQ-OPP-2018-0053. Applicant: BASF Corporation. Product Name: TerindaTM SC Termiticide/ Insecticide. Active ingredient: Insecticide-Broflanilide at 9.47%. Proposed Use: To kill subterranean termites outdoors around apartments, homes, restaurants, hospitals and nursing homes (non-patient areas), hotels and motels, mobile homes, office buildings, schools, transportation equipment (cargo trucks, trailers, and train cars ONLY), warehouses and other commercial and industrial buildings and in transportation equipment. Contact: RD.

13. File Symbol: 7969–URO. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: BASF Corporation. Product name: TeraxxaTM F4 Insecticide and Fungicide Seed Treatment. Active ingredient: Insecticide-Broflanilide at 1.55%, Fluxapyroxad at 0.78%, Pyraclostrobin at 1.55%, Triticonazole at 1.55%, and Metalaxyl at 0.93%. Proposed Use: Seed treatment for insect control in wheat (all types), barley, oats, rye, triticale, amaranth grain, buckwheat (all types), cañihua, chia, cram-cram, huauzontle, quinoa, and spelt. Contact: RD

14. File Symbol: 7969-URT. Docket ID number: EPA-HQ-OPP-2018-0053. Applicant: BASF Corporation. Product name: PT VediraTM Pressurized Insecticide. Active ingredient: Insecticide-Broflanilide at 0.20%. Proposed Use: To kill ants (excluding carpenter), bed bugs, crickets, Indian meal moths (adult and larvae), millipedes, silverfish, spiders (including black widow and brown recluse), and stored product pest beetles; and to control ants (foraging harvester and Pharaoh), beetles (Asian lady), cockroaches (German), flies (house and stable), kuzu bugs, and stink bugs

(brown marmorated) in and around Apartments, Campgrounds, Food storage areas, Homes, Hospitals**, Hotels, Meat packing and food processing plants, Motels, Nursing homes **, Resorts, Restaurants and other food handling establishments, Schools, Supermarkets, Transportation equipment (Airplanes—cargo areas only, Buses, Boats, Ships, Trains, and Trucks), Utilities, Warehouses and other commercial and industrial buildings. Contact: RD.

15. File Symbol: 7969-URU. Docket ID number: EPA-HQ-OPP-2018-0053. Applicant: BASF Corporation. Product name: VediraTM Pressurized Fly Bait. Active ingredient: Insecticide-Broflanilide at 0.125%. Proposed Use: To kill flies (blue bottle, filth, flesh, house, moth, phorid, and small fruit or vinegar flies) and house fly larvae in and around Commercial, residential, and industrial buildings and other manmade structures; Garbage or refuse bins and receptacles; or Other areas where flies may be a nuisance or health hazard: Apartments; Bakeries; Campgrounds; Carnivals; Circuses; Concert arenas; Condominiums; Confectionaries; County and state fair facilities; Dairy areas; Farm houses; Day care facilities; Festival grounds, Food handling establishments; Food processing plants; Food storage areas; Food vending structures; Garages; Golf courses; Grain mills; Granaries; Homes; Hospitals; Hotels; Housing and containment areas (i.e., Arenas, Barns, Cages, Hatcheries, Houses, Hutches, Kennels, Parlors, Pens, Sheds, Shelters, Stables) for animals (*i.e.*, Avian, Bovine, Canine, Equine, Feline, Hircine, Leporine, Murine, Porcine); Interiorscapes; Libraries; Marinas; Meat, poultry and egg processing facilities; Meat packing plants; Milk houses; Mobile homes; Motor homes; Motels; Museums; Nursing homes; Outdoor living areas; Pavilions; Porches; Research facilities; Resorts; Restaurants; Mobile food vendors; Parking ramps; Poultry facilities (including: Hatchery, Egg packaging, Breeding facilities, Houses); Public picnic areas; Public restrooms; Recreational rest areas; Residential backvards; Schools; Supermarkets; Tents or temporary shelters; Theme parks; Terminals; Transportation equipment (Buses, Barges, Boats, Ships, Trailers, Trains, Trucks); Utilities; Warehouses; Waysides; Wildlife refuge areas; Zoos. Contact: RD.

16. File Symbol: 86203–EI. Docket ID number: EPA–HQ–OPP–2018–0053. Applicant: Mitsui Chemicals Agro, Inc. (MCAG). Product name: Broflanilide Technical. Active ingredient:

Insecticide-Broflanilide at 99.68%. Proposed Use: For formulation into insecticides for 1) terrestrial food crops and crop groups: Brassica (Cole) Leafy Vegetables (Crop Group 5), Canola, Corn, Cotton, Fruiting Vegetables (Except Cucurbits) (Crop Group 8), Herbs and Spices (Crop Group 19), Leafy Vegetables (Except Brassica Vegetables) (Crop Group 4), Legume Vegetables (Succulent or Dried) (Crop Group 6), Soybean, Tea, and Tuberous and Corm Vegetables (Crop Subgroup 1C); and the following seed treatment uses: Cereal Grains (Crop Group 15), Tuberous and Corm Vegetables (Crop Subgroup 1), and Soybeans. 2) Non-crop uses: Food-handling establishments; indoor and outdoor residential and commercial as well as termiticide applications. Contact: RD

17. File Symbol: 80286–EI. Docket ID number: EPA–HQ–OPP–2018–0370. Applicant: ISCA Technologies, Inc., 1230 W. Spring St., Riverside, CA 92507. Product name: SPLAT FAW GL3. Active ingredients: Straight Chain Lepidopteran Pheromone—(Z)-7-Dodecenyl Acetate at 0.09%, (Z)-9-tetradecenyl acetate at 2.55%, and (Z)-11-hexadecenyl acetate at 0.36%. Proposed use: End-use product to be used as mating distruptant for lepidopteran species. Contact: BPPD.

18. File Symbol: 80286–E.O.. Docket ID number: EPA–HQ–OPP–2018–0370. Applicant: ISCA Technologies, Inc., 1230 W. Spring St., Riverside, CA 92507. Product name: SPLAT FAW GL4. Active ingredients: Straight Chain Lepidopteran Pheromone—(Z)-7-Dodecenyl Acetate at 0.12%, (Z)-9-tetradecenyl acetate at 3.40%, and (Z)-11-hexadecenyl acetate at 0.48%. Proposed use: End-use product to be used as mating distruptant for lepidopteran species. Contact: BPPD.

19. File Symbol: 80286–ET. Docket ID number: EPA–HQ–OPP–2018–0370. Applicant: ISCA Technologies, Inc., 1230 W. Spring St., Riverside, CA 92507. Product name: ISCA FAW MP. Active ingredients: Straight Chain Lepidopteran Pheromone—(Z)-7-Dodecenyl Acetate at 2.86%, (Z)-9-tetradecenyl acetate at 81.00%, and (Z)-11-hexadecenyl acetate at 11.44%. Proposed use: Manufacturing-use product for formulation into end-use products to be used as mating distruptants for lepidopteran species. Contact: BPPD.

20. File Symbol: 80286–GN. Docket ID number: EPA–HQ–OPP–2018–0370. Applicant: ISCA Technologies, Inc., 1230 W. Spring St., Riverside, CA 92507. Product name: SPLAT FAW GL5. Active ingredients: Straight Chain Lepidopteran Pheromone—(Z)-7-

Dodecenyl Acetate at 0.15%, (Z)-9-tetradecenyl acetate at 4.25%, and (Z)-11-hexadecenyl acetate at 0.60%. *Proposed use:* End-use product to be used as mating distruptant for lepidopteran species. *Contact:* BPPD.

Authority: 7 U.S.C. 136 et seq.

Dated: June 27, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018-15463 Filed 7-18-18; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2018-0008; FRL-9980-25]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before August 20, 2018.

ADDRESSES: Submit your comments, identified by the Docket Identification (ID) Number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- Hand Delivery: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at http://www.epa.gov/dockets/contacts.html.

 Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

Robert McNally, Biopesticides and Pollution Prevention Division (BPPD) (7511P), main telephone number: (703) 305–7090; email address: BPPDFRNotices@epa.gov, Michael Goodis, Registration Division (RD) (7505P), main telephone number: (703) 305–7090; email address: RDFRNotices@epa.gov. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

B. What should I consider as I prepare my comments for EPA?

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

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at http://www.epa.gov/dockets/comments.html.

II. Registration Applications

EPA has received applications to register new uses for pesticide products

containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

New Uses

- 1. EPA Registration Numbers: 100–895, 100–1259, 100–1211. Docket ID number: EPA–HQ–OPP–2018–0143. Applicant: The Interregional Research Project No. 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. Active ingredient: Abamectin. Product type: Insecticide. Proposed Use: Carrot, roots; Tropical and subtropical, small fruit, inedible peel, subgroup 24A; Leafy greens, subgroup 4–16A; Leaf petiole vegetable, subgroup 22B; Arugula; Garden cress; Upland cress; Celtuce; Fennel, Florence. Contact: RD.
- 2. EPA Registration Numbers: 100–895, 100–1259, 100–1211. Docket ID number: EPA–HQ–OPP–2018–0143. Applicant: Syngenta Crop Protection, LLC, P.O. Box 18300 Greensboro, NC 27419. Active ingredient: Abamectin. Product type: Insecticide. Proposed Use: Edible-podded legume vegetable, subgroup 6A; Succulent shelled pea and bean, subgroup 6B; Dried shelled pea and bean, subgroup 6C, except soybean. Contact: RD.
- 3. EPA Registration Number(s): 264–824, 264–825, and 264–1055. Docket ID number: EPA–HQ–OPP–2017–0531. Applicant: Bayer CropScience LP2, T.W. Alexander Dr., Research Triangle Park, NC 27709. Active ingredient: Prothioconazole. Product type: Fungicide. Proposed Use: Crop group expansion from current use on canola to Crop Subgroup 20A (Rapeseed subgroup). Contact: RD.
- 4. EPÂ Registration Number(s): 4787–55, 4787–61, 279–3557, 279–3588, 279–3594, and 279–3596. Docket ID number: EPA–HQ–OPP–2018–0297. Applicant: Cheminova A/S, P.O. Box 9, DK–7620, Lemvig, Denmark and on behalf of FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. Active ingredient: Flutriafol. Product type: Fungicide. Proposed Use: Alfalfa, Barley, Corn, and Rice. Contact: (RD).
- 5. *ĒPA Registration Numbers:* 62719–631, 62719–623, 62719–625. *Docket ID number:* EPA–HQ–OPP–2018–0179. *Applicant:* The Interregional Research Project No. 4 (IR–4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201 W, Princeton, NJ 08540. *Active ingredient:* sulfoxaflor. *Product type:* Insecticide. *Proposed Use:*

Artichoke, globe; Asparagus; Bushberry, subgroup 13–07B; Caneberry, subgroup 13–07A; Sunflower, subgroup 20B; Fruit, stone, group 12–12; Leafy greens subgroup 4–16A; Leaf petiole vegetable, subgroup 22B; Nut, tree, group 14–12; Vegetable, brassica, head and stem, group 5–16, except cauliflower; Brassica, leafy greens, subgroup 4–16B, except watercress; Celtuce; Fennel, Florence; and Kohlrabi. *Contact*: RD.

6. EPA Registration Numbers: 68539–3, 68539–4, 68539–7, 68539–9 and 68539–10. Docket ID number: EPA–HQ–OPP–2018–0256. Applicant: Bioworks, Inc. (d/b/a BioWorks), 100 Rawson Rd., Suite 205, Victor, NY 14564. Active ingredients: Trichoderma virens strain G–41 and/or Trichoderma harzianum Rifai strain T–22. Product type: Fungicide. Proposed use: For expanded field and greenhouse uses (e.g., overhead sprinkler chemigation). Contact: BPPD.

7. EPA Registration Number: 68539–8. Docket ID number: EPA–HQ–OPP–2018–0256. Applicant: Bioworks, Inc. (d/b/a BioWorks), 100 Rawson Rd., Suite 205, Victor, NY 14564. Active ingredient: Trichoderma virens strain G–41. Product type: Fungicide. Proposed use: For manufacturing of Trichoderma virens strain G–41 pesticide products with expanded field and greenhouse uses (e.g., overhead sprinkler chemigation). Contact: BPPD.

8. EPA Registration Number: 68539–12. Docket ID number: EPA–HQ–OPP–2018–0256. Applicant: Bioworks, Inc. (d/b/a BioWorks), 100 Rawson Rd., Suite 205, Victor, NY 14564. Active ingredient: Trichoderma harzianum Rifai strain T–22. Product type: Fungicide. Proposed use: For manufacturing of Trichoderma harzianum Rifai strain T–22 pesticide products with expanded field and greenhouse uses (e.g., overhead sprinkler chemigation). Contact: BPPD.

9. EPA Registration Numbers and File Symbol: 71512–26, 71512–27, 71512–GU. Docket ID number: EPA–HQ–OPP–2018–0194. Applicant: ISK Biosciences Corporation, 7470 Auburn Rd, Suite A, Concord, OH, 44077. Active Ingredient: Cyclaniliprole. Product type: Insecticide. Proposed Use: Citrus fruit (crop group 10–10); tuberous & corm vegetables (crop group 1C); and berry & small fruit (crop subgroups 13–07A, 13–07B, 13–07E, except grape, 13–07G). Contact: RD.

10. EPA Registration Number and File Symbols: 71512–27, 71512–GE, 71512–GG. Docket ID number: EPA–HQ–OPP–2018–0194. Applicant: ISK Biosciences Corporation, 7470 Auburn Rd, Suite A, Concord, OH, 44077. Active Ingredient: Cyclaniliprole. Product type:

Insecticide. *Proposed Use:* Indoor & outdoor ornamentals, Christmas trees, non-bearing fruit and nut trees, vines in shade houses, nurseries, and greenhouses. *Contact:* RD.

11. EPA Registration Number: 74054–1, 66222–47. Docket ID number: EPA–HQ–OPP–2018–0275. Applicant: Makhteshim AGAN of North America, INC., D/B/A/ADAMA, 3120 Highwoods Blvd., Suite 100 Raleigh, NC 27604. Active ingredient: clofentezine. Product type: Insecticide. Proposed use: Guava. Contact: RD.

12. EPA File Symbol: 80286–EA.
Docket ID number: EPA–HQ–OPP–
2018–0352. Applicant: ISCA
Technologies, Inc., 1230 W. Spring St.
Riverside, CA 92507. Active Ingredient:
Cypermethrin. Product type: insecticide.
Proposed use: palm trees (including date palms, coconut palms, oil palms and ornamental palms). Contact: RD.

Authority: 7 U.S.C. 136 et seq.

Dated: June 27, 2018.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2018–15448 Filed 7–18–18; 8:45 am]

BILLING CODE 6560-50-P

EXPORT-IMPORT BANK

[Public Notice: 2018-6012]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

EXIM's borrowers, financial institution policy holders and guaranteed lenders provide this form to U.S. exporters, who certify to the eligibility of their exports for EXIM support. For direct loans and loan guarantees, the completed form is required to be submitted at time of disbursement and held by either the guaranteed lender or EXIM. For MT insurance, the completed forms are held by the financial institution, only to be submitted to EXIM in the event of a claim filing.

EXIM uses the referenced form to obtain information from exporters

regarding the export transaction and content sourcing. These details are necessary to determine the value and legitimacy of EXIM financing support and claims submitted. It also provides the financial institutions a check on the export transaction's eligibility at the time it is fulfilling a financing request.

DATES: Comments must be received on or before September 17, 2018 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on www.regulations.gov (EIB 11–05) or by email to Mia.Johnson@exim.gov, or by mail to Mia L. Johnson, Export-Import Bank, 811 Vermont Ave. NW, Washington, DC 20571. The information collection tool can be reviewed at: https://www.exim.gov/sites/default/files/pub/pending/eib11-05.pdf.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 11–05 Exporter's Certificate for Loan Guarantee & MT Insurance Programs.

OMB Number: 3048–0043. Type of Review: Regular.

Need and Use: The information collected will allow EXIM to determine compliance and content for transaction requests submitted to the Export-Import Bank under its insurance, guarantee, and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 4.000.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 2,000 hours. Frequency of Reporting of Use: As required.

Government Expenses: Reviewing time per year: 67 hours. Average Wages per Hour: \$42.50. Average Cost per Year: \$2,847.50 (time*wages).

Benefits and Overhead: 20%. Total Government Cost: \$3,417.

Bassam Doughman,

IT Specialist.

[FR Doc. 2018-15422 Filed 7-18-18; 8:45 am]

BILLING CODE 6690-01-P

EXPORT-IMPORT BANK

[Public Notice 2018-6013]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its

continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

EXIM's financial institution policy holders provide this form to U.S. exporters, who certify to the eligibility of their exports for EXIM support. The completed forms are held by the financial institution policy holders, only to be submitted to EXIM in the event of a claim filing. A requirement of EXIM's policies is that the insured financial institution policy holder obtains a completed Exporter's Certificate at the time it provides financing for an export. This form will enable EXIM to identify the specific details of the export transaction. These details are necessary for determining the eligibility of claims for approval. EXIM staff and contractors review this information to assist in determining that an export transaction, on which a claim for non-payment has been submitted, meets all of the terms and conditions of the insurance coverage.

DATES: Comments must be received on or before September 17, 2018 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on www.regulations.gov (EIB 94–07) or by email Mia.Johnson@exim.gov, or by mail to Mia L. Johnson, Export-Import Bank, 811 Vermont Ave. NW, Washington, DC 20571. The form can be viewed at https://www.exim.gov/sites/default/files/pub/pending/eib-94-07.pdf.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 94–07 Exporters Certificate for Use with a Short Term Export Credit Insurance Policy.

OMB Number: 3048–0041.

Type of Review: Regular.

Need and Use: EXIM uses the referenced form to obtain exporter certification regarding the export transaction, U.S. content, non-military use, non-nuclear use, compliance with EXIM's country cover policy, and their eligibility to participate in USG programs. These details are necessary to determine the legitimacy of claims submitted. It also provides the financial institution policy holder a check on the export transaction's eligibility, at the time it is fulfilling a financing request.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 240. Estimated Time per Respondent: 15 minutes.

Annual Burden Hours: 60 hours.

Frequency of Reporting of Use: As required.

Government Expenses:

Reviewing time per year: 12 hours. Average Wages per Hour: \$42.50.

Average Cost per Year: \$510 (time*wages).

Benefits and Overhead: 20%. Total Government Cost: \$612.

Bassam Doughman,

IT Specialist.

[FR Doc. 2018–15424 Filed 7–18–18; 8:45 am]

BILLING CODE 6690-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary by email at Secretary@fmc.gov, or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the Federal Register. Copies of the agreements are available through the Commission's website (www.fmc.gov) or by contacting the Office of Agreements at (202) 523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 010979–064.
Agreement Name: Caribbean
Shipowners Association.

Parties: Crowley Caribbean Services LLC; Hybur Ltd.; King Ocean Services Limited, Inc.; Seaboard Marine Ltd.; Tropical Shipping & Construction Co., Ltd.; and Zim Integrated Shipping Services Ltd.

Filing Parties: Wayne Rohde, Cozen O'Connor.

Synopsis: The amendment deletes CMA CGM SA as a party to the Agreement.

Proposed Effective Date: 7/12/2018. Location: https://www2.fmc.gov/ FMC.Agreements.Web/Public/ AgreementHistory/1194.

Agreement No.: 011426–065.

Agreement Name: West Coast of
South America Discussion Agreement.

Parties: King Ocean Services Limited, Inc. and Seaboard Marine Ltd.

Filing Parties: Wayne Rohde, Cozen O'Connor.

Synopsis: The amendment deletes CMA CGM SA as a party to the Agreement.

Proposed Effective Date: 7/12/2018. Location: https://www2.fmc.gov/ FMC.Agreements.Web/Public/ AgreementHistory/939. Dated: July 16, 2018.

Rachel E. Dickon,

Secretary.

[FR Doc. 2018–15421 Filed 7–18–18; 8:45 am]

BILLING CODE 6731-AA-P

GENERAL SERVICES ADMINISTRATION

[Notice-MA-2018-06; Docket No. 2018-0002, Sequence No. 15]

Federal Travel Regulation (FTR); Relocation Allowances—Waiver of Certain Provisions of the FTR Chapter 302 for Official Relocation Travel to Locations in the U.S. Virgin Islands and Commonwealth of Puerto Rico Impacted by Hurricanes Irma and Maria

AGENCY: Office of Government-Wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of Federal Travel Regulation (FTR) Bulletin 18–07, Relocation Allowances—Waiver of certain provisions of the FTR Chapter 302 for official relocation travel to locations in the U.S. Virgin Islands and Commonwealth of Puerto Rico impacted by Hurricanes Irma and Maria.

SUMMARY: The purpose of this notice is to inform Federal agencies that certain provisions of the FTR governing official relocation travel expenses are temporarily waived for United States (U.S.) Virgin Islands and Commonwealth of Puerto Rico locations impacted by Hurricanes Irma and Maria. As a result of the storm damage caused by Hurricanes Irma and Maria, agencies should consider delaying all nonessential relocations to the affected areas given the statutory 120-day maximum for Temporary Quarters Subsistence Expenses (TQSE). Due to the lasting effects of the storm damage to these affected areas, finding lodging facilities and/or adequate meals may be difficult, and distances involved may be great, resulting in increased costs for relocation per diem expenses. FTR Bulletin 18-07 and all other FTR Bulletins can be found at www.gsa.gov/ ftrbulletin.

DATES: Applicable: July 19, 2018.

Applicability: The Bulletin is retroactively applicable for official relocation travel performed on or after September 7, 2017, the date of the Presidential Disaster Declaration DR–4335, to locations in the U.S. Virgin Islands affected by Hurricane Irma, and September 10, 2017, the date of the Presidential Disaster Declaration DR–4336 to locations in the Commonwealth of Puerto Rico affected by Hurricane

Irma. The FTR Bulletin expires once year from the respective applicable dates, unless extended or rescinded by this office.

The Bulletin is also retroactively applicable for official relocation travel performed on or after September 20, 2017, the date Presidential Disaster Declarations DR–4339 and DR–4340 were issued, to locations in the U.S. Virgin Islands and Commonwealth of Puerto Rico affected by Hurricane Maria. The FTR Bulletin will expire one year from the applicable date, unless extended or rescinded by this office.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. Rick Miller, Program Analyst, Office of Government-Wide Policy, Office of Asset and Transportation Management, at 202–501–3822, or by email at travelpolicy@gsa.gov. Please cite Notice of FTR Bulletin 18–07.

Dated: July 12, 2018.

Alexander Kurien,

Deputy Associate Administrator, Office of Asset and Transportation Management, Office of Government-Wide Policy.

[FR Doc. 2018-15398 Filed 7-18-18; 8:45 am]

BILLING CODE 6820-14-P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities: Proposed Collection; Comment Request; Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, OGE seeks comment on the development of a Generic Information Collection Request for the collection of qualitative feedback on agency service delivery for approval under the Paperwork Reduction Act. This notice announces OGE's intent to submit this collection to the Office of Management and Budget for approval and allows for an additional 30 days of public comment.

DATES: Consideration will be given to all comments received by August 20, 2018.

ADDRESSES: You may submit comments on this notice to the Office of Management and Budget, Attn: Desk Officer for OGE, via fax at 202–395–6974 or email at OIRA_Submission@omb.eop.gov. (Include reference to

"OGE Fast Track Generic Clearance comment" in the subject line of the message.)

FOR FURTHER INFORMATION CONTACT:

Grant Anderson at the U.S. Office of Government Ethics; telephone: 202–482–9318; TTY: 800–877–8339; FAX: 202–482–9237; Email: *Grant.Anderson@oge.gov.*

SUPPLEMENTARY INFORMATION:

Title: Fast Track Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: To be determined. Needs and Uses: The proposed information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the agency's commitment to improving service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions. but is not a statistical survey that yields quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

OGE expects to use various methods (e.g., focus groups, customer satisfaction surveys, comment cards), to solicit feedback. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public and other agency stakeholders. If this information is not collected, vital feedback from customers and stakeholders on the agency's services will be unavailable.

The agency will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are noncontroversial;
- The collections are focused on the awareness, understanding, attitudes, preferences, or experiences of the public

or other stakeholders in order to improve existing or future services, products, or communication materials;

- Personally identifiable information (PII) is collected only to the extent necessary;
- Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release to the public;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions;
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections submitted under this generic clearance will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

A Federal Register Notice with a 60-day comment period soliciting comments on this information collection was published on April 12, 2018 (83 FR 15837–15838). OGE did not receive any comments in response.

Current Action: New information collection request (generic).

Type of Review: New.

Affected Public: Individuals; Business or Other For-Profit Institutions; Not-For-Profit Institutions; State or Local Government.

Estimated Annual Number of Respondents: 45,000.

Projected average burden estimates for the next three years:

Average Expected Annual Number of Activities: 40.

Average Number of Respondents per Activity: 1,125.

Responses per Respondent: 1. Annual Responses: 45,000. Average Minutes per Response: 3 minutes.

Annual Burden Hours: 2,250 hours. Frequency: On occasion.

Request for Comments: Agency and public comment is again invited specifically on the need for and practical utility of this information collection, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The comments will become a matter of public record.

Approved: July 11, 2018.

David Apol,

General Counsel and Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2018–15411 Filed 7–18–18; 8:45 a.m.]

BILLING CODE 6345-03-P

GULF COAST ECOSYSTEM RESTORATION COUNCIL

[Docket No.: 107162018-1111-03]

Notice of Proposed Subaward Under a Council-Selected Restoration Component Award

AGENCY: Gulf Coast Ecosystem

Restoration Council. **ACTION:** Notice.

SUMMARY: The Gulf Coast Ecosystem Restoration Council (RESTORE Council) publishes notice of proposed subawards from the Mississippi Department of Environmental Quality (MDEQ) to the Mississippi Wildlife Federation and the Partnership for Gulf Coast Land Conservation, two Mississippi nonprofit organizations, for the purpose of education and outreach in accordance with the Sea Grant Education and Outreach (EOE) Award, as approved in the Initial Funded Priority List.

FOR FURTHER INFORMATION CONTACT:

Please send questions by email to joshua.easton@restorethegulf.gov.

SUPPLEMENTARY INFORMATION: Section 1321(t)(2)(E)(ii)(III) of the RESTORE Act

(33 U.S.C. 1321(t)(2)(E)(ii)(III)) and Treasury's implementing regulation at 31 CFR 34.401(b) require that, for purposes of awards made under the Council-Selected Restoration Component, a State or Federal award recipient may make a grant or subaward to or enter into a cooperative agreement with a nongovernmental entity that equals or exceeds 10 percent of the total amount of the award provided to the State or Federal award recipient only if certain notice requirements are met. Specifically, at least 30 days before the State or Federal award recipient enters into such an agreement, the Council must publish in the Federal Register and deliver to specified Congressional Committees the name of the recipient and subrecipient; a brief description of the activity, including its purpose; and the amount of the award. This notice accomplishes the Federal Register requirement.

Description of Proposed Action

As specified in the Initial Funded Priority List, which is available on the Council's website at https:// www.restorethegulf.gov/councilselected-restoration-component/fundedpriorities-list, RESTORE Act funds in the amount of \$750,000 will support the Sea Grant Education and Outreach (EOE) Award to MDEQ. As part of this project, MDEQ will provide a subaward in the amount of \$84,150 to the Mississippi Wildlife Federation for enhancement of the Mississippi Habitat Stewards Program. Through the subaward, the Mississippi Wildlife Federation will expand an existing curriculum that relays the ecosystem benefits of upstream land conservation, habitat restoration and water quality restoration. The expanded curriculum will be offered for three different targeted audiences at different levels: Habitat steward volunteers; youth, ages 9-12; and local high school environmental clubs.

MDEQ will also provide a subaward in the amount of \$99,050 to the Partnership for Gulf Coast Land Conservation (PGCLC). The PGCLC will conduct an outreach initiative that includes three components: The development of science-based communication products for use with a general audience that summarize and explain the benefits of land conservation in the Gulf coast region in lay terminology; field visits that bring together stakeholders to illustrate, in the field and by boat, the connectivity that land conservation practices along our coastal streams have to water quality in the northern Gulf of Mexico and to our marine and estuarine living resources;

and the development of a short digital film that illustrates the connection between riparian and wetland forests and marine and estuarine living resources in the northern Gulf of Mexico.

Keala J. Hughes,

 $\label{lem:constraint} \begin{tabular}{ll} Director of External Affairs \& Tribal Relations, \\ Gulf Coast Ecosystem Restoration Council. \\ \end{tabular}$

[FR Doc. 2018-15451 Filed 7-18-18; 8:45 am]

BILLING CODE 6560-58-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substance and Disease Registry

[60Day-18-18AJK Docket No. ATSDR-2018-0002]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments." ATSDR and the CDC National Center for Environmental Health (NCEH) will conduct a minimum of eight exposure assessments (EAs) at current or former military installations with known PFAS contamination in drinking water, groundwater, or another water source.

DATES: ATSDR must receive written comments on or before September 17, 2018.

ADDRESSES: You may submit comments, identified by Docket No. ATSDR-2018-0002 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. ATSDR will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS—D74, Atlanta, Georgia 30329; phone: 404–639–7570; Email: omb@cdc.gov.

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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in

comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected; and

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

5. Assess information collection costs.

Proposed Project

Per- or Polyfluoroalkyl Substances (PFAS) Exposure Assessments—NewAgency for Toxic Substances and Disease Registry (ATSDR) and the National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that have been used in industry and consumer products worldwide since the 1950s. Although some PFAS are no longer produced in the United States, they many remain in the environment and may impact people's health. Thus, PFAS are contaminants that have gained national prominence over the last decade.

Under Section 8006 of the Consolidated Appropriations Act, 2018, the Agency for Toxic Substances and Disease Registry and CDC National Center for Environmental Health (ATSDR/NCEH) are requesting a threevear Paperwork Reduction Act clearance for a new information collection request (ICR). ATSDR/NCEH will conduct EAs at current or former domestic military installations known to have PFAS in drinking water, groundwater, or any other sources of water. The annualized number of EAs assumes the following. ATSDR/NCEH will conduct a minimum of eight EAs, but ATSDR/NCEH may complete an additional seven for a total of 15 EAs. Therefore, ATSDR/NCEH anticipates conducting five PFAS EAs each year for three years.

All eligible respondents will be consented before being included in each EA. The consent forms will include adult consent, and parental permission and child assent forms, as appropriate. Each consented respondent will provide a serum and a urine sample. In addition, heads of households from ten percent of households using tap water for their drinking water will consent to provide tap water and indoor dust samples. The consent forms will include permission to store some biospecimens and environmental samples for future analysis and will include permission to recontact respondents for potential investigations or studies in the future. ATSDR will also collect contact information to provide respondents with their individual sampling results.

Household Eligibility Screener:
ATSDR/NCEH will conduct the PFAS
EAs in communities with populations
living on or near current or former
military installations. ATSDR/NCEH
will recruit a desired sample size of 379
respondents per EA (1,895 total per
year) using statistical household
sampling methods. Eligibility criteria for
individuals include specific age
intervals (i.e., children older than three

years given the lack of NHANES comparison data for younger children), lack of bleeding disorders that would prevent a blood draw, and time of residency (*i.e.*, at least one year in the home).

Applying an average U.S. household size of 2.5 members, per EA, ATSDR/NCEH will enroll respondents from 152 eligible households (379/2.5). To identify the 152 eligible households, we further assume a 65 percent household eligibility rate. This will require administering a 5-minute eligibility screener to 234 heads-of-households per EA (152*100/65), or to 1,170 heads-of-households per year (234 \times 5). The annual time burden requested for eligibility screening is 98 hours.

Exposure Assessment Questionnaire for Biological and Environmental Testing for Adults, Parents, or Children: ATSDR/NCEH will administer an exposure questionnaire to all consented respondents that includes questions associated with potential exposure to PFAS both inside and outside the home (e.g., work or school). In addition, the adult questionnaire also includes several questions associated with water use and flooring type while the child questionnaire includes questions regarding playing in soil; these questions are intended to evaluate potential exposure and to support the environmental testing. The time associated with administering the questionnaire and completing the biological sampling is approximately 30 minutes for 1,440 adults (720 hours). The time associated is 15 minutes for 264 parents responding for their children, 3-11 years old (66 hours), and for 191 children, 12-17 years old, who respond for themselves (48 hours). ATSDR/NCEH will use the questionnaire and laboratory results to identify likely exposure scenarios.

Household Recruitment Script for Environmental Sampling: The households providing environmental samples will be randomly selected from households that report using tap water for drinking water. ATSDR/NCEH will recruit 10 percent subset of these eligible households to collect tap water and indoor dust samples. Assuming a 65 percent response rate, ATSDR/NCEH will administer a 5-minute recruitment script to 23 heads-of households who are eligible to take part in each EA (152/ 10*100/65). The time required to administer the recruitment script is 5 minutes. This will result in annual recruitment from 117 heads-ofhouseholds and 10 hours for five EAs.

Environmental Sample Collection Form: Again, assuming a 65 percent response rate, to meet our sample size goal of 10 percent of eligible households, ATSDR/NCEH will consent and collect samples from approximately 15 households per EA or households annually (152*10/100*5). The average time burden is estimated as 15 minutes per response, or 19 hours annually.

ATSDR estimates the total annualized time burden is 961 hours. Participation

is voluntary, and there are no costs to respondents other than their time.

Public health professionals, environmental risk managers, and other decision makers can use EA results to make informed decisions about the sources and impact of PFAS contamination in environmental media within their own community and jurisdiction. The data will support their

recommendations for public health actions to reduce or eliminate harmful levels of PFAS in the local environment. These EAs are not intended to yield information about PFAS exposure that will be generalized beyond the defined boundaries of each investigation; however, ATSDR/NCEH will use these EA findings to inform a future national PFAS health study.

ESTIMATED ANNUALIZED BURDEN HOURS

| Type of respondent | Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|--|---|-----------------------|------------------------------------|---|--------------------|
| Potential EA Heads-of-Households EA Adults | Household Eligibility Screener Exposure Questionnaire for Biological and Environmental Testing (Adults). | 1,170 1,440 | 1 1 | 5/60 30/60 | 98 720 |
| EA Parents | EA Questionnaire for Biological Testing (Child). | 264 | 1 | 15/60 | 66 |
| EA Children | EA Questionnaire for Biological Testing (Child). | 191 | 1 | 15/60 | 48 |
| EA Heads-of-Households | Household Recruitment Script for Environmental Sampling. | 117 | 1 | 5/60 | 10 |
| | Environmental Sample Collection Form. | 76 | 1 | 15/60 | 19 |
| Total | | | | | 961 |

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–15437 Filed 7–18–18; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1224]

Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Use of Electronic Health Record Data in Clinical Investigations." The guidance provides recommendations for sponsors, clinical investigators, contract research organizations (CROs), institutional review boards (IRBs), and other interested parties on the use of electronic health record (EHR) data in FDA-regulated clinical investigations.

The guidance finalizes the draft guidance issued in May 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on July 19, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA—2016—D—1224 for "Use of Electronic Health Record Data in Clinical Investigations; Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or 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 selfaddressed adhesive label to assist the office in processing your requests. See

the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document

FOR FURTHER INFORMATION CONTACT:

Cheryl Grandinetti, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3348, Silver Spring, MD 20993-0002, 301-796-2500, cheryl.grandinetti@ fda.hhs.gov; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911, ocod@fda.hhs.gov; or Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5458, Silver Spring, MD 20993-0002, 1-800-638-2041 or 301-796-5528, bakul.patel@fda.hhs.gov or DigitalHealth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Use of Electronic Health Record Data in Clinical Investigations." The guidance is intended to assist sponsors, clinical investigators, CROs, IRBs, and other interested parties on the use of EHR data in FDA-regulated clinical investigations. In an effort to modernize and streamline clinical investigations, the goals of the guidance are to facilitate the use of EHR data in clinical investigations and to promote the interoperability of EHR and EDC systems.

In the Federal Register of May 17, 2016 (81 FR 30540), FDA announced the availability of the draft guidance. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. A summary of changes includes clarifying the following: (1) The types of clinical investigations using EHR data as source data that fall under the scope of the guidance; (2) recommendations on the use of EHR and EDC systems that are interoperable or fully integrated; (3) recommendations on the use of certified and noncertified EHR technology; (4) how electronic source data principles apply to EHR data used as source data; and (5) inspection, recordkeeping, and record retention requirements. This guidance finalizes the draft guidance issued in May 2016.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Use of Electronic Health Record Data in Clinical

Investigations." 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This 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 guidance pertains to sponsors, clinical investigators, CROs, IRBs, and other interested parties who use EHR data as electronic source data in FDA-regulated clinical investigations and who send certain information to FDA or others or who keep certain records and make them available to FDA inspectors. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910-0303; the collections of information in 21 CFR part 50 have been approved under OMB control number 0910-0755; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014; and the collections of information in 21 CFR 812.140 have been approved under OMB control number 0910-0078. The use of EHRs as a source of data, as described in the guidance, would not result in any new costs, including capital costs or operating and maintenance costs, because sponsors and others already have experience and are experienced with using computer-based equipment and software necessary to be consistent with the guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/
GuidanceComplianceRegulatory
Information/Guidances/default.htm,
https://www.fda.gov/MedicalDevices/
DeviceRegulationandGuidance/
GuidanceDocuments/default.htm, or
https://www.regulations.gov.

Dated: July 13, 2018.

Leslie Kux,

 $Associate\ Commissioner\ for\ Policy.$ [FR Doc. 2018–15390 Filed 7–18–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0809]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration,

HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that EPIDIOLEX (cannabidiol oral solution) manufactured by GW Research Ltd., meets the criteria for a priority review

FOR FURTHER INFORMATION CONTACT:

Althea Cuff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4061, Fax: 301–796–9856, email: althea.cuff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA has determined that EPIDIOLEX (cannabidiol oral solution) manufactured by GW Research Ltd., meets the criteria for a priority review voucher. EPIDIOLEX (cannabidiol oral solution) is indicated for the treatment of seizures associated with Dravet Syndrome or Lennox-Gastaut Syndrome in patients 2 years of age and older.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseases Conditions/RarePediatricDiseasePriority VoucherProgram/default.htm. For further information about EPIDIOLEX (cannabidiol oral solution), go to the

"Drugs@FDA" website at https:// www.accessdata.fda.gov/scripts/cder/ daf/.

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2018–15393 Filed 7–18–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2567]

E17 General Principles for Planning and Design of Multiregional Clinical Trials; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration,

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "E17 General Principles for Planning and Design of Multiregional Clinical Trials." The guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The guidance describes general principles for planning and designing multiregional clinical trials (MRCTs). The guidance is intended to increase the acceptability of data from MRCTs as the primary source of evidence supporting marketing approval in global regulatory submissions and thereby facilitate more efficient drug development and earlier access to medicines.

DATES: The announcement of the guidance is published in the **Federal Register** on July 19, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any

confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA—2016—D—2567 for "E17 General Principles for Planning and Design of Multiregional Clinical Trials; International Council for Harmonisation." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Aloka Chakravarty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 21, Rm. 3514, Silver Spring, MD 20993–0002, 301–796–1655; or R. Douglas Pratt, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002, 301–796–2640.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, regulatory authorities and industry associations from around the world have participated in many important initiatives to promote international harmonization of regulatory requirements under the ICH. FDA has participated in several ICH meetings designed to enhance harmonization and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the FDA; the Japanese Ministry of Health, Labour, and Welfare: the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidance.

In the **Federal Register** of September 9, 2016 (81 FR 62506), FDA published a notice announcing the availability of a draft guidance entitled "E17 General Principles for Planning and Design of Multi-Regional Clinical Trials." The notice gave interested persons an

opportunity to submit comments by November 8, 2016.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies in November 2017.

The guidance provides guidance on general principles for planning and designing MRCTs. MRCTs conducted according to the guidance will investigate treatment effects in overall populations with multiple ethnic factors (intrinsic and extrinsic factors as described in Appendix A of the ICH guidance entitled "E5 Ethnic Factors in the Acceptability of Foreign Clinical Data") and evaluate the consistency of treatment effects across populations. The guidance explicitly states that MRCTs are planned under the assumption that the treatment effect applies to the entire target population, particularly to the regions included in the trial. The concept of "consistency of treatment effect" across regions is defined in the text and in the glossary, and the terms "pooled populations" and "pooled regions" are also added to the glossary. The guidance further clarifies that prespecified strategies for pooling regions and/or subpopulations provide flexibility in sample-size allocation to regions, and that the strategies facilitate the assessment of consistency in treatment effects across regions.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "E17 General Principles for Planning and Design of Multiregional Clinical Trials." 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the document at https://www.regulations.gov, https://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/Guidances/default.htm, or https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory
Information/Guidances/default.htm.

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.
[FR Doc. 2018–15395 Filed 7–18–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2016-D-0643]

Labeling for Biosimilar Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Labeling for Biosimilar Products." This guidance is intended to help applicants develop draft labeling for proposed biosimilar products. The recommendations for prescription drug labeling in this guidance pertain only to the prescribing information (commonly referred to as the package insert), except for certain recommendations pertaining to FDAapproved patient labeling (e.g., Patient Information, Medication Guide, and Instructions for Use). This guidance provides an overview of FDA's recommendations for labeling for biosimilar products. This guidance finalizes the draft guidance issued on April 4, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on July 19, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2016–D–0643 for "Labeling for Biosimilar Products; Guidance for Industry; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY **INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6522, Silver Spring, MD 20993, 301–796– 1042; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Labeling for Biosimilar Products." The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), enacted as part of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148) on March 23, 2010, created an abbreviated licensure pathway for biological products demonstrated to be biosimilar to or interchangeable with an FDAlicensed reference product. Section 351(k) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or supplement for a proposed interchangeable product. Under section 351(k) of the PHS Act, a

proposed biological product that is demonstrated to be biosimilar to a reference product can rely on certain existing scientific knowledge about the safety, purity, and potency of the reference product to support licensure, and this is reflected in the approach to biosimilar product labeling.

In this guidance, FDA outlines its recommendations for biosimilar product labeling. A demonstration of biosimilarity means, among other things, that FDA has determined that there are no clinically meaningful differences between the proposed product and the reference product in terms of safety, purity, and potency. Accordingly, biosimilar applicants should incorporate relevant data and information from the reference product labeling, with appropriate modifications as recommended in the guidance.

This guidance finalizes the draft guidance issued on April 4, 2016. Changes made to the guidance took into consideration the comments received, as well as requests regarding the requirements for and/or contents of biosimilar labeling made in the following citizen petitions: FDA-2015-P-2000 (submitted by AbbVie, Inc.), FDA-2015-P-4529 (submitted by a group of institutional investors including the United Auto Workers (UAW) Retiree Medical Benefits Trust), and FDA-2015-P-0776 (submitted by the Pharmaceutical Research and Manufacturers of America and the Biotechnology Industry Organization) (these citizen petitions are available at https://www.regulations.gov). Editorial changes were made primarily for clarification.

In the **Federal Register** of April 4, 2016 (81 FR 19194), FDA announced the availability of the draft guidance for industry "Labeling for Biosimilar Products." FDA requested comment on whether FDA-approved patient labeling (e.g., Patient Information, Medication Guide, and Instructions for Use) should include a biosimilarity statement similar to the statement described in section IV.C.1 of the draft guidance. Several comments agreed with inclusion of the biosimilarity statement; one comment disagreed. FDA considered the comments received, but decided not to recommend inclusion of a biosimilarity statement in FDA-approved patient labeling at this time.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Labeling for Biosimilar Products." 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This 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 for the submission of a biologics license application under section 351(k) of the PHS Act have been approved under OMB control number 0910-0719; the collections of information in 21 CFR 201.56 and 201.57 for the submission of labeling have been approved under OMB control number 0910-0572; the collections of information in 21 CFR part 208 for Medication Guides have been approved under OMB control number 0910-0393; the collections of information in 21 CFR 312.47 for meetings with FDA have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 600 for the submission of adverse experience reporting for licensed biological products and general records have been approved under OMB control number 0910-0308; and the collections of information in 21 CFR part 601 for the submission of labeling in a biologics license application or supplement to a biologics license application have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory
Information/Guidances/default.htm, or https://www.regulations.gov.

Dated: July 13, 2018.

Leslie Kux,

Associate Commissioner for Policy. [FR Doc. 2018–15391 Filed 7–18–18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. FDA-2018-D-2326]

Field Alert Report Submission: Questions and Answers; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration,

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Field Alert Report Submission: Questions and Answers." This draft guidance, when finalized, will provide the Agency's current thinking regarding the requirements for submission of field alert reports (FARs) by applicants of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) and will outline FDA's recommendations for FAR submissions to help increase their consistency and relevancy. The draft guidance also addresses certain frequently asked questions about FARs.

DATES: Submit either electronic or written comments on the draft guidance by September 17, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https:// www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as

 Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

 For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-2326 for "Field Alert Report Submission: Questions and Answers; Draft Guidance for Industry," Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday

through Friday.

 Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/ fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to https:// www.regulations.gov and insert the

docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Mamta Gautam-Basak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 2508, Silver Spring, MD 20993-0002, 301-796-0712; Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911; or Rachel Harrington, Office of Regulatory Affairs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4339, Silver Spring, MD 20993-0002, 410-779-5441.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Field Alert Report Submission: Questions and Answers." The FAR regulations found in 21 CFR 314.81(b)(1) and 314.98(b) establish an early warning system to help protect patient health. Under these regulations, NDA and ANDA applicants must submit certain information to FDA about distributed drug products regulated by the Center for Drug Evaluation and Research or the Center for Biologics Evaluation and Research.

The draft guidance addresses the FAR submission requirements and focuses on topics such as the incidents and

possible/actual quality issues that require submission of a FAR, the contents of the FAR, who submits the FAR, and when, where, and how they should submit it. The draft guidance also addresses followup and final FARs, which are not required under § 314.81(b), and recommends their submission to inform FDA of the status of root cause investigations and corrective actions taken, if any.

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 field alert report submissions. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information that 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 314 have been approved under OMB control number 0910-0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https:// www.fda.gov/Drugs/Guidance ComplianceRegulatoryInformation/ Guidances/default.htm, https:// www.fda.gov/BiologicsBloodVaccines/ *GuidanceComplianceRegulatory* Information/default.htm, or https:// www.regulations.gov.

Dated: July 13, 2018.

Leslie Kux.

Associate Commissioner for Policy. [FR Doc. 2018-15389 Filed 7-18-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIDA International Research and Training Program Support Services (1158).

Date: August 9, 2018.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, 301–827–5817, mcguireso@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: July 13, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–15358 Filed 7–18–18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Newborn Screening Translational Research Network (NBSTRN) August 13, 2018.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6710 B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Sathasiva B. Kandasamy, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20892, (301) 435–6680, skandasa@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: July 13, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–15357 Filed 7–18–18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

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 Neurological Disorders and Stroke Special Emphasis Panel; Planning Grant to Develop Phase III Clinical Trials for LBD.

Date: August 6, 2018.

Time: 3:00 p.m. to 4:30 p.m. Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, ana.olariu@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: July 13, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–15359 Filed 7–18–18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given for the meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention National Advisory Council (CSAP NAC) on August 1, 2018.

The Council was established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and Director, CSAP concerning matters relating to the activities carried out by and through the Center and the policies respecting such activities.

The meeting will be open to the public and will include the discussion of the substance use prevention workforce and opioid use prevention. The meeting will also include updates on CSAP program developments.

The meeting will be held in Rockville, Maryland. Attendance by the public will be limited to the space available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before one week prior to the meeting. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations should notify the contact on or before one week prior to the meeting. Five minutes maximum will be allotted for each presentation.

To attend onsite, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Committees' website, http://nac.samhsa.gov/Registration/

meetingsRegistration.aspx, or communicate with the CSAP Council's Designated Federal Officer (see contact information below).

Substantive program information may be obtained after the meeting by accessing the SAMHSA Committee website, http://nac.samhsa.gov/, or by contacting the Designated Federal Officer.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention, National Advisory Council.

Date/Time/Type: August 1, 2018, from 9:30 a.m. to 5:00 p.m. EDT: (OPEN)

Place: SAMHSA, 5600 Fishers Lane, Room 5N54, Rockville, MD 20852, Adobe Connect webcast: https:// samhsa-csap.adobeconnect.com/nac/.

Contact: Matthew J. Aumen, Designated Federal Officer, SAMHSA CSAP NAC, 5600 Fishers Lane, Rockville, MD 20852, Telephone: 240– 276–2440, Fax: 301–480–8480, email: matthew.aumen@samhsa.hhs.gov.

Carlos Castillo,

Committee Management Officer, SAMHSA.
[FR Doc. 2018–15450 Filed 7–18–18; 8:45 am]
BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4366-DR; Docket ID FEMA-2018-0001]

Hawaii; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Hawaii (FEMA–4366–DR), dated May 11, 2018, and related determinations.

DATES: This amendment was issued June 14, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Hawaii is hereby amended to include Individual Assistance for the following area among those areas determined to have been adversely affected by the event declared a major

disaster by the President in his declaration of May 11, 2018.

Hawaii County for Individual Assistance (already designated for Public Assistance, including direct Federal assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance— Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–15388 Filed 7–18–18; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4373-DR; Docket ID FEMA-2018-0001]

Oklahoma; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Oklahoma (FEMA–4373–DR), dated June 25, 2018, and related determinations.

DATES: The declaration was issued June 25, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 25, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Oklahoma resulting from wildfires during the period of April 11–20, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Oklahoma.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Traci L. Brasher, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Oklahoma have been designated as adversely affected by this major disaster:

Custer, Dewey, Harmon, Roger Mills, and Woodward Counties for Public Assistance.

All areas within the State of Oklahoma are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034 Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance-Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs: 97.036. Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–15371 Filed 7–18–18; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-B-1838]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 17, 2018.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location https://www.fema.gov/preliminary floodhazarddata and the respective

Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at https://msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA–B–1838, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are

provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/ srp overview.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location https:// www.fema.gov/preliminaryfloodhazard data and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at https://msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community Community map repository address

Utah County, Utah and Incorporated Areas

Project: 15–08–0730S Preliminary Date: March 31, 2014 and January 30, 2018

| City of Alpine City of American Fork City of Cedar Hills City of Draper City of Highland | City Hall, 51 East Main Street, American Fork, UT 84003. City Hall, 10246 North Canyon Road, Cedar Hills, UT 84062. City Hall, 1020 East Pioneer Road, Draper, UT 84020. |
|--|--|
| City of Lehi | City Hall, 153 North 100 East, Lehi, UT 84043. |

| Community | Community map repository address | | |
|--|---|--|--|
| City of Mapleton City of Orem City of Payson City of Provo City of Salem City of Saratoga Springs | City Center, 351 West Center Street, Provo, UT 84601. | | |
| City of Spanish Fork City of Springville City of Vineyard Town of Genola Unincorporated Areas of Utah County | City Hall, 40 South Main Street, Spanish Fork, UT 84660. City Hall, 110 South Main Street, Springville, UT 84663. City Hall, 240 East Gammon Road, Vineyard, UT 84058. Town Office, 74 West 800 South, Genola, UT 84655. Community Development Department, 51 South University Avenue Suite 117, Provo, UT 84601. | | |

[FR Doc. 2018–15384 Filed 7–18–18; 8:45 am] BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: New or modified Base (1percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address

listed in the table below and online through the FEMA Map Service Center at https://msc.fema.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at https://msc.fema.gov.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|--|--------------------------------------|--|---|----------------------|------------------|
| Connecticut: New Haven (FEMA Docket No.: B– 1821). | City of New Haven (18– 01–0359P). | The Honorable Toni N. Harp, Mayor, City of New Haven, 165 Church Street, New Haven, CT 06510. | Planning Department, 165 Church Street, New Haven, CT 06510. | June 22, 2018 | 090084 |
| Florida: Broward (FEMA | City of Hollywood (17– | The Honorable Josh Levy, Mayor, | City Hall, 2600 Hollywood Boule- | June 20, 2018 | 125113 |
| Docket No.: B- 1821). | 04–3432P). | City of Hollywood, P.O. Box 229405, Hollywood, FL 33022. | vard, Hollywood, FL 33020. | , , | |

| | I | | | I | |
|--|---|---|---|----------------------|------------------|
| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
| Collier (FEMA Docket No.: B-1816). | Unincorporated areas of Collier County (18– 04–0709P). | The Honorable Penny Taylor, Chair, Collier County Board of Commis- sioners, 3299 Tamiami Trail East, Suite 303, Naples, FL 34112. | Collier County Administrative Building, 3301 East Tamiami Trail, Building F, 1st Floor, Naples, FL 34112. | June 14, 2018 | 120067 |
| Lee (FEMA Docket No.: B-1821). | City of Sanibel, (17–04–7625P). | The Honorable Kevin Ruane, Mayor, City of Sanibel, 800 Dun- lop Road, Sanibel, FL 33957. | Planning Department, 800 Dunlop Road, Sanibel, FL 33957. | June 25, 2018 | 120402 |
| Lee (FEMA Docket No.: B-1816). | Town of Fort Myers Beach (18–04– 0640P). | The Honorable Dennis C. Boback, Mayor, Town of Fort Myers Beach, 2525 Estero Boulevard, Fort Myers Beach, FL 33931. | Community Development Department, 2525 Estero Boulevard, Fort Myers Beach, FL 33931. | June 14, 2018 | 120673 |
| Manatee (FEMA Docket No.: B- 1816). | City of Bradenton (18– 04–1119P). | The Honorable Wayne H. Poston, Mayor, City of Bradenton, 101 Old Main Street West, Bradenton, FL 34205. | City Hall, 101 Old Main Street West, Bradenton, FL 34205. | June 15, 2018 | 120155 |
| Manatee (FEMA Docket No.: B- 1816). | Unincorporated areas of Manatee County (18– 04–1119P). | The Honorable Betsy Benac, Chair, Manatee County Board of Com- missioners, P.O. Box 1000, Bra- denton, FL 34206. | Manatee County Building and Development Services Department, 1112 Manatee Avenue West, Bradenton, FL 34205. | June 15, 2018 | 120153 |
| Miami-Dade (FEMA Docket No.: B– 1821). | City of Miami (17-04-7381P). | The Honorable Francis Suarez, Mayor, City of Miami, 3500 Pan American Drive, Miami, FL 33133. | Building Department, 444 Southwest 2nd Avenue, Miami, FL 33133. | June 20, 2018 | 120650 |
| Monroe (FEMA Docket No.: B– 1821). | Unincorporated areas of Monroe County (18– 04–0838P). | The Honorable David Rice, Mayor, Monroe County Board of Com- missioners, 9400 Overseas High- way, Suite 210, Marathon, FL 33050. | Monroe County Building Department, 9805 Overseas Highway, Suite 300, Marathon, FL 33050. | June 15, 2018 | 125129 |
| Pinellas (FEMA Docket No.: B- 1821). | City of Clearwater (18– 04–0912P). | The Honorable George N. Cretekos, Mayor, City of Clearwater, P.O. Box 4748, Clearwater, FL 33758. | Engineering Department, 100 South Myrtle Avenue, Suite 220, Clear- water, FL 33758. | June 25, 2018 | 125096 |
| Sarasota (FEMA Docket No.: B– 1821). | Unincorporated areas of Sarasota County (18– 04–1102P). | The Honorable Nancy Detert, Chair, Sarasota County Board of Com- missioners, 1660 Ringling Boule- vard, Sarasota, FL 34236. | Sarasota County Planning and Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240. | June 15, 2018 | 125144 |
| Seminole (FEMA Docket No.: B- 1821). | City of Oviedo (17–04– 2581P). | The Honorable Dominic Persampiere, Mayor, City of Oviedo, 400 Alexandria Boule- vard, Oviedo, FL 32765. | Public Works Department, 1655 Evans Street, Oviedo, FL 32765. | June 15, 2018 | 120293 |
| Seminole (FEMA Docket No.: B– 1821). | Unincorporated areas of Seminole County (17–04–2581P). | The Honorable John Horan, Chairman, Seminole County Board of Commissioners, 1101 East 1st Street, Sanford, FL 32771. | Seminole County Development Review Division, 1101 East 1st Street, Sanford, FL 32771. | June 15, 2018 | 120289 |
| Maryland: Prince George's (FEMA Docket No.: B-1821). | Unincorporated areas of Prince George's County (17–03– 2338P). | The Honorable Rushern L. Baker, III, Prince George's County Executive, 14741 Governor Oden Bowie Drive, Upper Marlboro, MD 20772. | Prince George's County Department of Stormwater Management, 1801 McCormick Drive, Largo, MD 20774. | June 20, 2018 | 245208 |
| North Carolina: Wake (FEMA Dock- et No.: B-1821). | City of Raleigh (16–04– 2597P). | The Honorable Nancy McFarlane, Mayor, City of Raleigh, P.O. Box 590, Raleigh, NC 27602. | Stormwater Management Division, 1 Exchange Plaza, Suite 304, Ra- leigh, NC 27601. | June 27, 2018 | 370243 |
| Wake (FEMA Dock- et No.: B-1821). | City of Raleigh (16–04– 2710P). | The Honorable Nancy McFarlane, Mayor, City of Raleigh, P.O. Box 590, Raleigh, NC 27602. | Stormwater Management Division, 1 Exchange Plaza, Suite 304, Ra- leigh, NC 27601. | June 27, 2018 | 370243 |
| Wake (FEMA Docket No.: B-1821). | Town of Knightdale (16–04–2597P). | The Honorable James Roberson, Mayor, Town of Knightdale, 950 Steeple Square Court, Knightdale, NC 27545. | Town Hall, 950 Steeple Square Court, Knightdale, NC 27545. | June 27, 2018 | 370241 |
| Oklahoma: Grady (FEMA Docket No.: B-1816). | City of Chickasha (17– 06–2589P). | Mr. John Noblitt, Manager, City of Chickasha,117 North 4th Street, Chickasha, OK 73018. | City Hall, 117 North 4th Street, Chickasha, OK 73018. | June 11, 2018 | 400234 |
| Pennsylvania: Bedford (FEMA Docket No.: B- 1821). | Borough of Hyndman (17–03–2585P). | The Honorable Newton Huffman, Mayor, Borough of Hyndman, P.O. Box 74, Hyndman, PA | Borough Hall, 3945 Center Street, Hyndman, PA 15545. | June 25, 2018 | 420121 |
| Bedford (FEMA Docket No.: B– 1821). | Township of London- derry (17–03–2585P). | 15545. The Honorable Stephen Stouffer, Chairman, Township of London- derry Board of Supervisors, P.O. | Township Hall, 4303 Hyndman Road, Hyndman, PA 15545. | June 25, 2018 | 421345 |
| Lancaster (FEMA Docket No.: B– 1821). | Township of Manheim (17–03–1486P). | Box 215, Hyndman, PA 15545. Mr. Sean P. Molchany, Manager- Secretary, Township of Manheim, 1840 Municipal Drive, Lancaster, PA 17601. | Township Hall, 1840 Municipal Drive, Lancaster, PA 17601. | June 15, 2018 | 420556 |
| Lancaster (FEMA Docket No.: B– 1816). | Township of Warwick (18–03–0392P). | Mr. Daniel L. Zimmerman, Manager, Township of Warwick, P.O. Box 308, Lititz, PA 17543. | Township Hall, 315 Clay Road, Lititz, PA 17543. | June 15, 2018 | 421786 |
| Lycoming (FEMA Docket No.: B– 1821). | Township of Loyalsock (18–03–0265P). | Mr. William Burdett, Manager, Township of Loyalsock, 2501 East 3rd Street, Williamsport, PA 17701. | Township Hall, 2501 East 3rd Street, Williamsport, PA 17701. | June 19, 2018 | 421040 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|--|---|---|--|----------------------|------------------|
| Somerset (FEMA Docket No.: B– 1821). | Borough of Rockwood (18–03–0266P). | The Honorable Melissa Cramer, Mayor, Borough of Rockwood, 669 Somerset Avenue, Rock- wood, PA 15557. | Borough Hall, 669 Somerset Avenue, Rockwood, PA 15557. | June 20, 2018 | 422045 |
| South Carolina: Berkley (FEMA Docket No.: B– 1816). | Unincorporated areas of Berkley County (17– 04–5508P). | The Honorable William W. Peagler, III, Berkley County Supervisor, P.O. Box 6122, Moncks Corner, SC 29461. | Berkeley County Planning and Zon- ing Department, 1003 Highway 52, Moncks Corner, SC 29461. | June 14, 2018 | 450029 |
| Charleston (FEMA Docket No.: B- 1821). | City of Folly Beach (17– 04–4686P). | The Honorable Timothy M. Goodwin, Mayor, City of Folly Beach, P.O. Box 48, Folly Beach, SC 29439. | Building Department, 21 Center Street, Folly Beach, SC 29439. | June 20, 2018 | 455415 |
| South Dakota: Lawrence (FEMA Docket No.: B– 1816). Texas: | City of Spearfish (18– 08–0192P). | The Honorable Dana Boke, Mayor, City of Spearfish, 625 North 5th Street, Spearfish, SD 57783. | City Hall, 625 North 5th Street, Spearfish, SD 57783. | June 13, 2018 | 460046 |
| Bexar (FEMA Docket No.: B-1821). | City of San Antonio (17–06–0568P). | The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283. | Transportation and Capital Improve- ments Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204. | June 25, 2018 | 480045 |
| Collin (FEMA Docket No.: B–1821). | Town of Plano (17-06-3654P). | The Honorable Harry LaRosiliere, Mayor, City of Plano, 1520 K Avenue, Plano, TX 75074. | Engineering Department, 1520 K Avenue, Plano, TX 75074. | June 15, 2018 | 480140 |
| Collin (FEMA Docket No.: B-1816). | Town of Prosper (18-06-0355P). | The Honorable Ray Smith, Mayor, Town of Prosper, P.O. Box 307, Prosper, TX 75078. | Engineering Services Department, 409 East 1st Street, Prosper, TX 75078. | June 14, 2018 | 480141 |
| El Paso (FEMA Docket No.: B- 1821). | City of El Paso (18–06– 0747P). | Mr. Tommy Gonzales, Manager, City of El Paso, 300 North Camp- bell Street, El Paso, TX 79901. | City Hall, 801 Texas Avenue, El Paso, TX 79901. | June 18, 2018 | 480214 |
| El Paso (FEMA Docket No.: B– 1816). | City of El Paso (18–06– 0885P). | Mr. Tommy Gonzales, Manager, City of El Paso, 300 North Camp- bell Street, El Paso, TX 79901. | City Hall, 801 Texas Avenue, El Paso, TX 79901. | June 12, 2018 | 480214 |
| Fort Bend (FEMA Docket No.: B– 1816). | City of Rosenberg (17– 06–3041P). | The Honorable William T. "Bill" Benton, Mayor, City of Rosenberg, P.O. Box 32, Rosenberg, TX 77471. | City Hall, 2110 4th Street, Rosenberg, TX 77471. | June 12, 2018 | 480232 |
| Fort Bend (FEMA Docket No.: B- 1816). | Unincorporated areas of Fort Bend County (17–06–3041P). | The Honorable Robert Hebert, Fort Bend County Judge, 401 Jackson Street, Richmond, TX 77469. | Fort Bend County Engineering Department, 301 Jackson Street, Richmond, TX 77469. | June 12, 2018 | 480228 |
| Harris (FEMA Dock- et No.: B-1821). | Unincorporated areas of Harris County (17– 06–1728P). | The Honorable Edward M. Emmett, Harris County Judge, 1001 Pres- ton Street, Suite 911, Houston, TX 77002. | Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77002. | June 11, 2018 | 480287 |
| Harris (FEMA Dock- et No.: B-1821). | Unincorporated areas of Harris County (17– 06–3887P). | The Honorable Edward M. Emmett, Harris County Judge, 1001 Pres- ton Street, Suite 911, Houston, TX 77002. | Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77002. | June 11, 2018 | 480287 |
| Harris (FEMA Docket No.: B-1821). | Unincorporated areas of Harris County (18– 06–0276P). | The Honorable Edward M. Emmett, Harris County Judge, 1001 Pres- ton Street, Suite 911, Houston, TX 77002. | Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77002. | June 18, 2018 | 480287 |
| Tarrant (FEMA Docket No.: B- 1821). | City of Fort Worth (17– 06–4262P). | The Honorable Betsy Price, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102. | Transportation and Public Works Department, 200 Texas Street, Fort Worth, TX 76102. | June 25, 2018 | 480596 |
| Travis (FEMA Dock- et No.: B-1816). | City of Pflugerville (17–06–3914P). | The Honorable Victor Gonzales, Mayor, City of Pflugerville, P.O. Box 589, Pflugerville, TX 78691. | Development Services Department, 201–B East Pecan Street, Pflugerville, TX 78691. | June 18, 2018 | 481028 |
| Utah: Box Elder (FEMA Docket No.: B-1816). | City of Perry City (17– 08–1022P). | The Honorable Kevin Jeppsen, Mayor, City of Perry City, 3005 South 1200 West,Perry City, UT 84302. | City Hall, 3005 South 1200 West, Perry City, UT 84302. | June 14, 2018 | 490010 |
| Virginia: Fairfax (FEMA Docket No.: B-1821). | Unincorporated areas of Fairfax County (17–03–2338P). | Mr. Bryan Hill, Fairfax County Executive, 12000 Government Center Parkway, Fairfax, VA 22035. | Fairfax County Government Center, 12000 Government Center Park- way, Suite 449, Fairfax, VA 22035. | June 20, 2018 | 515525 |
| Wyoming: Teton (FEMA Docket No.: B-1816). | Unincorporated areas of Teton County (17– 08–0693P). | The Honorable Mark Newcomb, Chairman, Teton County Board of Commissioners, P.O. Box 3594, Jackson, WY 83001. | Teton County Engineering Department, 320 South King Street, Jackson, WY 83001. | June 14, 2018 | 560094 |

[FR Doc. 2018–15386 Filed 7–18–18; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4374-DR; Docket ID FEMA-2018-0001]

Maryland; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Maryland (FEMA–4374–DR), dated June 25, 2018, and related determinations.

DATES: The declaration was issued June 25, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated June 25, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the "Stafford Act"), as follows:

I have determined that the damage in certain areas of the State of Maryland resulting from severe storms and flooding during the period of May 15–19, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 et seq. (the "Stafford Act"). Therefore, I declare that such a major disaster exists in the State of Maryland.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Emily Breslin, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Maryland have been designated as adversely affected by this major disaster:

Frederick and Washington Counties for Public Assistance.

All areas within the State of Maryland are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance— Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–15397 Filed 7–18–18; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4365-DR: Docket ID FEMA-2018-0001]

Hawaii; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Hawaii (FEMA–4365–DR), dated May 8, 2018, and related determinations.

DATES: This amendment was issued June 27, 2018.

FOR FURTHER INFORMATION CONTACT:

Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833. **SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Hawaii is hereby amended to include Individual Assistance for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 8, 2018.

The City and County of Honolulu and Kaua'i County for Individual Assistance (already designated for Public Assistance). The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance-Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households-Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters): 97.039. Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency. [FR Doc. 2018–15396 Filed 7–18–18; 8:45 am]

BILLING CODE 9111-23-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: New or modified Base (1percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at https://msc.fema.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed

since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP)

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances

that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at https://msc.fema.gov.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|--|---|--|---|----------------------|------------------|
| California: | City of Corona (17– | The Honorable Karen Spiegel, | City Hall, 400 South Vicentia Avenue, Co- | Jun. 14, 2018 | 060250 |
| (FEMA Dock- et No.: B- 1812). | 09–2752P). | Mayor, City of Corona, 400 South Vicentia Avenue, Co- rona, CA 92882. | rona, CA 92882. | | |
| Riverside (FEMA Dock- et No.: B- 1812). | Unincorporated Areas of Riverside County (17–09– 2752P). | The Honorable Chuck Washington, Chairman, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501. | Riverside County, Flood Control and Water Conservation District, 1995 Mar- ket Street, Riverside, CA 92501. | Jun. 14, 2018 | 060245 |
| Florida: Duval (FEMA Docket No.: B–1809). | City of Jacksonville (17–04–6334P). | The Honorable Lenny Curry, Mayor, City of Jacksonville, 117 West Duval Street, Suite 400, Jacksonville, FL 32202. | City Hall, 117 West Duval Street, Jacksonville, FL 32202. | May 10, 2018 | 120077 |
| Hawaii: Honolulu (FEMA Docket No.: B–1812). | City and County of Honolulu (18–09– 0118P). | The Honorable Kirk Caldwell, Mayor, City and County of Honolulu, 530 South King Street Room 306, Honolulu, HI 96813. | Department of Planning and Permitting, 650 South King Street, Honolulu, HI 96813. | May 29, 2018 | 150001 |
| Idaho: | | | | | |
| Ada (FEMA Docket No.: B-1812). | City of Kuna (17– 10–1636P). | The Honorable Joe Stear, Mayor, City of Kuna, P.O. Box 13, Kuna, ID 83634. | City Hall, 329 West 3rd Street, Kuna, ID 83634. | Jun. 7, 2018 | 160174 |
| Ada (FEMA Docket No.: B-1812). | Unincorporated Areas of Ada County (17–10– 1636P). | The Honorable David L. Case, Chairman, Ada County Board of Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702. | Ada County Courthouse, 200 West Front Street, Boise, ID 83702. | Jun. 7, 2018 | 160001 |
| Ada (FEMA Docket No.: B-1812). | Unincorporated Areas of Ada County (18–10– 0284X). | The Honorable David L. Case, Chairman, Ada County Board of Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702. | Ada County Courthouse, 200 West Front Street, Boise, ID 83702. | Jun. 8, 2018 | 160001 |
| Illinois: Cook (FEMA Docket No.: B-1809). | Unincorporated Areas of Cook County (16–05– 7359P). | The Honorable Toni Preckwinkle The Honorable Toni Preckwinkle, President, Cook County Board, 118 North Clark Street, Room 537, Chicago, IL 60602. | Cook County Building and Zoning Department, 69 West Washington Street, 21st Floor, Chicago, IL 60602. | May 18, 2018 | 170054 |

| State and county | Location and case No. | Chief executive officer of community | Community map repository | Date of modification | Community No. |
|--|---|---|--|----------------------|------------------|
| Cook (FEMA Docket No.: B-1809). | Village of Alsip (16– 05–7359P). | The Honorable John D. Ryan, Mayor, Village of Alsip, 4500 West 123rd Street, Alsip, IL 60803. | Village Office, 4500 West 123rd Street, Alsip, IL 60803. | May 18, 2018 | 170055 |
| Cook (FEMA Docket No.: B-1809). | Village of Crestwood (16-05-7359P). | The Honorable Louis Presta, Mayor, Village of Crestwood, 13840 South Cicero Avenue, | Village Hall, 13840 South Cicero Avenue, Crestwood, IL 60418. | May 18, 2018 | 170080 |
| McHenry (FEMA Docket No.: B-1812). | Unincorporated Areas of McHenry County (18–05– 2003P). | Crestwood, IL 60418. The Honorable Jack D. Franks, Chairman, McHenry County Board, County Government Center, 2200 North Seminary Avenue, Woodstock, IL 60098. | County Government Center, 2200 North Seminary Avenue, Woodstock, IL 60098. | June 14, 2018 | 170732 |
| McHenry (FEMA Docket No.: B-1812). | Village of Port Barrington (18-05-2003P). | The Honorable Shannon Yeaton, Village President, Village of Port Barrington, 69 South Circle Avenue, Port Barrington, IL 60010. | Village Hall, 69 South Circle Avenue, Port Barrington, IL 60010. | June 14, 2018 | 170478 |
| Indiana: Lake (FEMA Docket No.: B– 1809). | City of Hammond (17–05–6621P). | The Honorable Thomas M. McDermott, Jr. Mayor, City of Hammond, Hammond City Hall, 5925 Calumet Avenue, Hammond, IN 46320. | City Hall, 5925 Calumet Avenue, Hammond, IN 46320. | May 4, 2018 | 180134 |
| lowa: Bremer (FEMA Docket No.: B- 1812). | City of Waverly (18– 07–0164P). | The Honorable Charles D. Infelt, Mayor, City of Waverly, 200 1st Street Northeast, Waverly, IA 50677. | City Hall, 200 1st Street Northeast, Waverly, IA 50677. | Jun. 1, 2018 | 190030 |
| Kansas: Johnson (FEMA Docket No.: B-1812). | City of Olathe (17– 07–2080P). | The Honorable Michael Copeland, Mayor, City of Olathe, P.O. Box 768, Olathe, KS 66051. | City Hall, Olathe Planning Office, 100 West Santa Fe Drive, Olathe, KS 66061. | Jun. 1, 2018 | 200173 |
| Minnesota: Anoka (FEMA Docket No.: B-1812). | City of Lino Lakes (17–05–5610P). | The Honorable Jeff Reinert, Mayor, City of Lino Lakes, 600 Town Center Parkway, Lino Lakes, MN 55014. | City Hall, 600 Town Center Parkway, Lino Lakes, MN 55014. | May 30, 2018 | 270015 |
| Missouri: Christian (FEMA Docket No.: B-1812). | City of Nixa (17-07- 1573P). | The Honorable Brian E. Steele, Mayor, City of Nixa, 715 West Mount Vernon Street, Nixa, MO 65714. | City Hall, 715 West Mount Vernon Street, Nixa, MO 65714. | May 10, 2018 | 290078 |
| Clay (FEMA Docket No.: B-1809). | City of Gladstone (17–07–1263P). | The Honorable R.D. Mallams, Mayor, City of Gladstone, City Hall, 7010 North Holmes Street, Gladstone, MO 64118. | City Hall, 7010 North Holmes Street, Gladstone, MO 64118. | May 11, 2018 | 290091 |
| Nevada: Douglas (FEMA Docket No.: B-1812). | Unincorporated Areas of Douglas County (17–09– 2481P). | The Honorable Barry Penzel, Chairman, Board of Commis- sioners, Douglas County, P.O. Box 218, Minden, NV 89423. | Douglas County, Community Develop- ment, 1594 Esmeralda Avenue, Minden, NV 89423. | Jun. 7, 2018 | 320008 |
| Oregon: Marion (FEMA Docket No.: B-1812). | City of Salem (17– 10–1422P). | The Honorable Chuck M. Bennett, Mayor, City of Salem, City Hall, 555 Liberty Street Southeast, Room 220, Salem, OR 97301. | Public Works Department, 555 Liberty Street Southeast, Room 325, Salem, OR 97301. | May 29, 2018 | 410167 |
| Marion (FEMA Docket No.: B-1812). | Unincorporated Areas of Marion County (17–10– 1422P). | Mr. Sam Brentano, Commissioner, Marion County, 555 Court Street Northeast, Suite 5232, Salem, OR 97309. | Marion County, Department of Planning, 315 Lancaster Drive Northeast, Salem, OR 97305. | May 29, 2018 | 410154 |
| Puerto Rico:, Puerto Rico (FEMA Dock- et No.: B-1809). | Commonwealth of Puerto Rico (17–02–1123P). | The Honorable Luis García Pelatti, President, Planning Board, Minillas Government Center, P.O. Box 41119, San Juan, PR 00940. | Puerto Rico Planning Board, Minillas Government Center, North Building, East Diego Avenue, Stop 22, San Juan, PR 00940. | May 10, 2018 | 720000 |
| Texas: Tarrant (FEMA Docket No.: B-1809). | City of Euless (17– 06–4048P). | The Honorable Linda Martin, Mayor, City of Euless, 201 North Ector Drive, Euless, TX 76039. | City Hall, 201 North Ector Drive, Euless, TX 76039. | May 18, 2018 | 480593 |
| Washington: King (FEMA Docket No.: B-1809). | City of Issaquah (17–10–0929P). | The Honorable Fred Butler, Mayor, City of Issaquah, P.O. Box 1307, Issaquah, WA 98027. | Department of Public Works, City Hall, 1775 12th Avenue Northwest, Issaquah, WA 98027. | May 11, 2018 | 530079 |

[FR Doc. 2018–15385 Filed 7–18–18; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-B-1841]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before October 17, 2018.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location https://www.fema.gov/preliminary floodhazarddata and the respective

Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at https://msc.fema.gov for comparison.

You may submit comments, identified by Docket No. FEMA–B–1841, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) patrick.sacbibit@fema.dhs.gov; or visit the FEMA Map Information eXchange (FMIX) online at https://www.floodmaps.fema.gov/fhm/fmx_main.html.

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are

provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at https://www.floodsrp.org/pdfs/ srp overview.pdf.

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location https:// www.fema.gov/preliminaryfloodhazard data and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at https://msc.fema.gov for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, "Flood Insurance.")

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community Community map repository address Hill County, Texas and Incorporated Areas Project: 14-06-1543S Preliminary Date: February 15, 2018 City of Abbott City Hall, 208 East Walnut Street, Abbott, TX 76621. City of Covington City Hall, 402 Gathings Avenue, Covington, TX 76636. City of Hillsboro Community Development Department, 214 East Elm Street, Hillsboro, TX 76645. City Hall, 134 North Hill Street, Itasca, TX 76055. City of Itasca Hill County Courthouse, John W. Erwin Annex, 200 East Franklin Unincorporated Areas of Hill County Street, Suite 9, Hillsboro, TX 76645.

| Community | Community map repository address | | |
|--|---|--|--|
| McLennan County, Texas and Incorporated Areas Project: 14–06–1543S Preliminary Date: February 15, 2018 | | | |
| City of Bellmead | City Hall, 3015 Bellmead Drive, Bellmead, TX 76705. City Hall, 1115 Wilbanks Drive, Hallsburg, TX 76705. Planning and Community Development, 103 North Hewitt Drive, Suite E. Hewitt, TX 76643. | | |
| City of Lacy-Lakeview City of Leroy City of Riesel City of Robinson City of Ross City of Waco | City Hall, 111 West Lyndale Drive, Robinson, TX 76706. | | |
| City of West | City Hall, 110 North Reagan Street, West, TX 76691. McLennan County Records Building, 215 North 5th Street, Room 130, Waco, TX 76701. | | |

[FR Doc. 2018–15387 Filed 7–18–18; 8:45 am] BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

U.S. Fish and Wildlife Service

[FWS-HQ-R-2017-N183; FXRS85110900000-XXX-FF09R40000]

Draft Long-Range Transportation Plans for U.S. Fish and Wildlife Service Lands in Regions 2, 6, and 8

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of three draft long-range transportation plans for public review and comment. These draft long-range transportation plans outline strategies for improving and maintaining transportation assets that provide access to Service-managed lands in Region 2 (Arizona, New Mexico, Oklahoma, and Texas), Region 6 (Colorado, Kansas, Montana, North Dakota, South Dakota, Utah, and Wyoming), and Region 8 (California and Nevada) over the next 20 years.

DATES: We must receive written comments on or before August 20, 2018. **ADDRESSES:** *Document Review:* If you wish to review these draft plans, you

may obtain copies by visiting the following websites:

- Region 2: https://ecos.fws.gov/ ServCat/Reference/Profile/87706
- Region 6: https://ecos.fws.gov/ ServCat/Reference/Profile/87709
- Region 8: https://ecos.fws.gov/ ServCat/Reference/Profile/87710

Alternatively, you may contact Laura Whorton, Acting Transportation Branch Chief, National Wildlife Refuge System, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, Bailey's Crossroads, VA 22041 (phone: 703–358–1752).

Submitting Comments: If you wish to comment on any or all of the plans, you may submit your comments in writing by any one of the following methods:

• *U.S. mail:* Acting Transportation Branch Chief, at the above address.

• Hand-delivery: Acting Transportation Branch Chief Analyst, at the above address.

- Fax: 703-358-1752.
- Email: laura whorton@fws.gov. For additional information about submitting comments, see the Public Availability of Comments section

FOR FURTHER INFORMATION CONTACT:

Laura Whorton, at the above address, phone number, or email.

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we make the draft long-range transportation plans (LRTPs) for Regions 2, 6, and 8 of the U.S. Fish and Wildlife Service available for public review and comment. When finalized, the LRTPs will apply to Servicemanaged lands in Region 2 (Arizona, New Mexico, Oklahoma, and Texas), Region 6 (Colorado, Kansas, Montana, North Dakota, South Dakota, Utah, and Wyoming), and Region 8 (California and Nevada).

Background

The Fixing America's Surface
Transportation (FAST) Act (Pub. L. 114–
94) requires that all Federal land
management agencies conduct longrange transportation planning in a
manner that is consistent with
metropolitan planning organizations
and State departments of transportation
planning. We initiated these LRTPs to
bring the Service into compliance with

the FAST Act and to achieve the following goals:

- Establish a defensible structure for sound transportation planning and decision-making;
- Establish a vision, mission, goals, and objectives for transportation planning in each of these three Service Regions;
- Implement coordinated and cooperative transportation partnerships in an effort to improve the Service's transportation infrastructure;
- Integrate transportation planning and funding for national wildlife refuges and national fish hatcheries into existing and future Service management plans and strategies;
- Increase awareness of alternative transportation systems and associated benefits:
- Develop best management practices for transportation improvements on Service lands; and
- Serve as a pilot project for the implementation of a region-level transportation planning process within the Service.

LRTP Mission, Goals, and Objectives

Through a collaborative effort, the National Wildlife Refuge System and the Fish and Aquatic Conservation Program, in cooperation with the planning and visitor services programs within these three Regions, have contributed to defining the mission, goals, and objectives presented in this document. The resulting mission, goals, and objectives are intended to provide a systematic approach to guide the process for evaluating and selecting transportation improvement programs for the Service lands in these Regions. These guiding principles have shaped the development, conclusions, and recommendations of these LRTPs. While each Region's specific mission, vision,

goals, and objectives differ slightly, they are substantively similar.

Mission: To support the Service's mission by connecting people to fish, wildlife, and their habitats through strategic implementation of transportation programs.

Goals and Objectives: Each of these long-range transportation plans has six substantively similar goals: Safety; access, mobility, and connectivity; asset management; environmental protection; visitor experience; and partnership. Region 8 has an additional seventh goal: Planning. Under each goal, each Region presents distinct objectives that move the Service to the goal. Please see the individual draft LRTPs for more information.

Next Steps

After the comment period ends, the Service will analyze the comments received and consider them in preparation of final LRTPs.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Gregory J. Sheehan,

Principal Deputy Director, U.S. Fish and Wildlife Service.

[FR Doc. 2018–15415 Filed 7–18–18; 8:45 am] BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R8-ES-2017-N132; FXES11130000-189-FF08E00000]

Endangered and Threatened Wildlife and Plants; Draft Recovery Plan for the Southern California Distinct Population Segment of the Mountain Yellowlegged Frog (Rana muscosa)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce the availability of the Draft Recovery Plan for the Southern California Distinct Population Segment of the Mountain Yellow-legged Frog (*Rana muscosa*) for public review and comment. The draft

recovery plan includes objective, measurable criteria, and site-specific management actions as may be necessary to reclassify the species from endangered to threatened and also for removal from the Federal List of Endangered and Threatened Wildlife.

DATES: We must receive any comments on the draft recovery plan on or before

September 17, 2018.

ADDRESSES: Document availability: You may obtain a copy of the recovery plan from our website at http://www.fws.gov/endangered/species/recovery-plans.html. Alternatively, you may contact the Carlsbad Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2177 Salk Avenue, Suite 250, Carlsbad, California 92008 (telephone 760–431–9440).

Comment submission: If you wish to comment on the draft recovery plan, you may submit your comments in writing by any one of the following methods:

- *U.S. mail:* Field Supervisor, at the above address;
- Hand-delivery: Carlsbad Fish and Wildlife Office, at the above address; or
- Email: fw8cfwocomments@fws.gov. For additional information about submitting comments, see the "Public Comments Solicited" section below.

FOR FURTHER INFORMATION CONTACT: Mendel Stewart, Field Supervisor, at the above street address or telephone number (see ADDRESSES).

SUPPLEMENTARY INFORMATION:

Background

Recovery of endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of our endangered species program and the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 et seq.). Recovery means improvement of the status of listed species to the point at which listing is no longer necessary under the criteria specified in section 4(a)(1) of the Act. The Act requires the development of recovery plans for listed species, unless such a plan would not promote the conservation of a particular species.

Pursuant to section 4(f) of the Act, a recovery plan must, to the maximum extent practicable, include (1) A description of site-specific management actions as may be necessary to achieve the plan's goals for the conservation and survival of the species; (2) objective, measurable criteria which, when met, would support a determination under section 4(a)(1) that the species should be removed from the List of Endangered and Threatened Species; and (3)

estimates of the time and costs required to carry out those measures needed to achieve the plan's goal and to achieve intermediate steps toward that goal.

The Service has revised its approach to recovery planning; the revised process is called Recovery Planning and Implementation (RPI). The RPI process is intended to reduce the time needed to develop and implement recovery plans, increase recovery plan relevancy over a longer timeframe, and add flexibility to recovery plans so they can be adjusted to new information or circumstances. Under RPI, a recovery plan will include statutorily required elements (objective, measurable criteria, site-specific management actions, and estimates of time and costs), along with a concise introduction and our strategy for how we plan to achieve species recovery. The RPI recovery plan is supported by a separate Species Status Assessment, or in cases such as this one, a species biological report that provides the background information and threat assessment, which are key to recovery plan development. The essential component to flexible implementation under RPI is producing a separate working document called the Recovery Implementation Strategy (implementation strategy). The implementation strategy steps down from the more general description of actions described in the recovery plan to detail the specific, near-term activities needed to implement the recovery plan. The implementation strategy will be adaptable by being able to incorporate new information without having to concurrently revise the recovery plan, unless changes to statutory elements are required.

The Service listed the southern California distinct population segment of mountain yellow-legged frog (Rana muscosa) (hereafter "southern R. muscosa'') as endangered in 2002 (67 FR 44382, July 2, 2002), and critical habitat was designated for the species in 2006 (71 FR 54344, September 14, 2006). Historically, southern R. muscosa was widely distributed in at least 166 known populations in watersheds across four mountain ranges in southern California. Currently, the species is restricted to 10 small, isolated populations in the headwaters of streams or tributaries within the San Gabriel, San Bernardino, and San Jacinto Mountains. Primary habitat for the southern R. muscosa includes streams with permanent (perennial) water that have steep gradients with numerous pools, rapids, and small waterfalls. The smallest creeks are likely not inhabited by southern R. muscosa

because they lack adequate depth to provide refuge or overwintering habitat.

Southern Rana muscosa is impacted by a number of threats, including: Recreational activities (hiking, mountain climbing, camping, swimming, stocking of trout resulting in predation, and suction dredge mining for gold), dumping of trash and release of toxic or hazardous materials into occupied stream reaches, wildfire, predatory nonnative species (trout), the potential for disease, threats associated with small population size (genetic, demographic, and environmental stochasticity, and natural catastrophes), illegal marijuana cultivation, fire management activities, nonnative plants, climate change, and contaminants.

Recovery Strategy

The purpose of a recovery plan is to provide a framework for the recovery of a species so that protection under the Act is no longer necessary. A recovery plan includes scientific information about the species and provides criteria that enable us to gauge whether downlisting or delisting the species is warranted. Furthermore, recovery plans help guide our recovery efforts by describing actions we consider necessary for each species' conservation and by estimating time and costs for implementing needed recovery measures.

The goal of this recovery plan is to control or ameliorate impacts from current threats to the southern *Rana muscosa* such that the taxon no longer requires protections afforded by the Act and, therefore, warrants delisting. Continued outreach with our partners is needed to ensure long-term protections are afforded to the southern *R. muscosa* and its habitat. The site-specific management actions identified in the draft recovery plan are as follows:

(1) Conduct research to inform management actions throughout the range of the species;

(2) Create and implement a protocol for rangewide surveys and monitoring;

- (3) Ameliorate Factor A threats associated with present or threatened destruction, modification, or curtailment of the habitat or range throughout each of the three Recovery Units:
- (4) Ameliorate Factor C threats associated with predation and disease in each of the three Recovery Units;
- (5) Ameliorate Factor E threats associated with other natural or manmade factors affecting the continued existence of southern Rana muscosa in each of the three Recovery Units;

(6) Use reestablishment and population augmentation to increase abundance and expand distribution in the wild.

Public Comments Solicited

We solicit written comments on the draft recovery plan described in this notice. All comments received by the date specified in **DATES** will be considered in development of a final recovery plan for southern *Rana muscosa*. You may submit written comments and information by mail, email, or in person to the Carlsbad Fish and Wildlife Office at the above address (see **ADDRESSES**).

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We developed this recovery plan and publish this notice under the authority of section 4(f) of the Act, 16 U.S.C. 1533(f).

Angela Picco,

Acting Regional Director, Pacific Southwest Region.

[FR Doc. 2018–15362 Filed 7–18–18; 8:45 am]
BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[DOI-2018-0004; 18XD4523WC DS68644000 DWCHF0000.000000 DQ.FPPJB.18000000]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary, Interior. **ACTION:** Notice of a modified system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of the Interior proposes to modify the Department of the Interior system of records titled, "Payroll, Attendance, Retirement, and Leave Records—Interior, DOI–85." This system of records allows the Department of the Interior to manage human resources and payroll functions; ensure proper payment for salary and benefits; track time worked, leave, or other

absences for reporting and compliance purposes; and meet regulatory requirements such as specialized pay, garnishments, and special appointment programs. The Department of the Interior is updating this system of records notice to (1) add new proposed routine uses, (2) modify existing routine uses to provide clarification, (3) modify the categories of records and categories of individuals covered by the system, and (4) update system location, authority for maintenance of the system, storage, retrievability, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, and records source categories. This modified system will be included in the Department of the Interior's inventory of record systems.

DATES: This modified system will be effective upon publication. New or modified routine uses will be effective August 20, 2018. Submit comments on or before August 20, 2018.

ADDRESSES: You may submit comments, identified by docket number DOI–2018–0004, by any of the following methods:

- Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.
- Hand-delivering comments to Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240.
- Email: DOI_Privacy@ios.doi.gov. All submissions received must include the agency name and docket number. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW, Room 7112, Washington, DC 20240, email at DOI_Privacy@ ios.doi.gov or by telephone at (202) 208–1605.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of the Interior (DOI), Interior Business Center (IBC) maintains the "Payroll, Attendance, Retirement, and Leave Records—Interior, DOI–85" system of records. This system helps DOI manage human resources and payroll functions; ensure proper payment for salary and benefits; track time worked, leave, or other absences for reporting and compliance purposes;

and meet regulatory requirements such as specialized pay, garnishments, and special appointment programs. DOI uses the integrated Federal Personnel and Payroll System (FPPS) and supporting systems to manage these payroll, time and attendance, and human capital management functions, meet regulatory requirements, and prepare reports to other Federal agencies including the Department of the Treasury and the Office of Personnel Management. The DOI payroll, attendance, retirement, and leave records described in this system of records notice form a part of the information contained in FPPS. Some personnel records contained in the FPPS may be covered under OPM/ GOVT-1, General Personnel Records, the government-wide system of records notice published by the Office of Personnel Management.

The DOI IBC is a Federal agency shared services provider that provides payroll and personnel processing services to internal and external customers, including its bureaus and offices and other Federal agency customers, through FPPS and its supporting systems. FPPS creates and generates the full life cycle of personnel transactions; allows for edits and updates of personnel and payroll data; and manages the regulatory requirements. Federal agency customers enter into agreements with the DOI IBC to host customer payroll and personnel data in the FPPS, and process payroll and personnel transactions on the customer's behalf. FPPS has interconnections with other Federal agencies; private organizations; Federal agency customers; state, city and county governments; and IBC internal systems that allow IBC to perform required transactions to fulfill its responsibilities to process payroll, personnel actions, and related functions.

Although DOI hosts and processes payroll and personnel transactions on beȟalf of IBĈ customers, each customer retains ownership and control over its own records and is responsible for meeting requirements under the Privacy Act for the collection, maintenance and sharing of their records. Federal agency customers have published their own system of records notices for their employees' payroll and personnel related records hosted or processed by DOI. Individuals seeking access to, notification or correction of their records owned and maintained by external Federal agency customers must submit their requests to the employing Federal agency customer that owns the records in accordance with the applicable system of records notice

published by that Federal agency customer.

DOI is publishing this revised notice to reorganize the sections and update section titles in accordance with Office of Management and Budget (OMB) Circular A-108; describe the purpose of the system; and provide general and administrative updates to the system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, storage, retrievability, safeguards, retention and disposal, system manager and address, notification procedures, records access and contesting procedures, and records source categories sections. Additionally, DOI is modifying existing routine uses to provide clarity and transparency. Routine use A was modified to further clarify disclosures to the Department of Justice or other Federal agencies when necessary in relation to litigation or judicial proceedings. Routine uses B, C, K, N, O, V, W, Z, EE, and GG have been modified to provide additional clarification on external organizations and circumstances where disclosures are proper and necessary to facilitate payroll and personnel functions or to comply with Federal requirements.

DOI is proposing to add new routine uses HH through UU to facilitate sharing of information with agencies and organizations to ensure the efficient and effective management of personnel data and proper payment of salary and benefits for employees, promote the integrity of the records in the system, or carry out a statutory responsibility of the DOI or the Federal Government. Proposed routine use HH facilitates sharing of information with the Executive Office of the President to resolve issues concerning individual's records. Routine use II facilitates payroll and personnel functions under a crossservicing agreement with other Federal agencies. Routine use JJ allows sharing of information to effectively manage Federal personnel functions related to complaints, claims and appeals initiated by employees. Routine use KK facilitates sharing of information to process or reconcile employees' unemployment claims, benefits, and related functions. Routine use LL facilitates sharing of information with carriers to process or reconcile survivor annuity or health benefits claims. Routine use MM allows DOI to share information to resolve issues or errors that may affect pay and leave in order to ensure an individual's personnel and payroll data is processed accurately. Routine use NN ensures the efficient and effective conduct of the Federal Government, to meet statutory

obligations to ensure integrity during the administration of benefits programs, eligibility for Federally-funded or administered benefit programs, tax administration, and to prevent fraud or attempted fraud. Routine use OO facilitates sharing of information with Congress in its oversight role to help improve performance and ensure accountability of the Federal Government and to meets its constitutional responsibilities. Routine use PP allows sharing of wage information with the Department of Health and Human Services as required under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. Routine uses QQ and RR allow DOI to share information with appropriate Federal agencies or entities when reasonably necessary to respond to a breach of personally identifiable information and to prevent, minimize, or remedy the risk of harm to individuals or the Federal Government. or assist an agency in locating individuals affected by a breach in accordance with OMB Memorandum M-17-12, "Preparing for and Responding to a Breach of Personally Identifiable Information." Routine use SS allows organizations authorized and required by law to perform audits or oversight operations to ensure accurate and effective personnel and payroll functions, proper payment for salary and benefits. Routine uses TT and UU allow sharing of information with a court, grand jury, tribunal, or other administrative or adjudicative body for the resolution of any legal dispute involving records in the system.

II. Privacy Act

The Privacy Act of 1974, as amended, embodies fair information practice principles in a statutory framework governing the means by which Federal agencies collect, maintain, use, and disseminate individuals' records. The Privacy Act applies to records about individuals that are maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The Privacy Act defines an individual as a United States citizen or an alien lawfully admitted for permanent residence. Individuals may request access to their own records that are maintained in a system of records in the possession or under the control of DOI by complying with DOI Privacy Act regulations at 43 CFR part 2, subpart K, and following the procedures outlined

in the Records Access, Contesting Record, and Notification Procedures sections of this notice.

The Privacy Act requires each agency to publish in the **Federal Register** a description denoting the existence and character of each system of records that the agency maintains and the routine uses of each system. The revised Payroll, Attendance, Retirement, and Leave Records system of records notice is published in its entirety below. In accordance with 5 U.S.C. 552a(r), DOI has provided a report of this modified system of records to the Office of Management and Budget and to Congress.

III. Public Participation

You should be aware your entire comment including your personal identifying information, such as your address, phone number, email address, or any other personal identifying information in your comment, may be made publicly available at any time. While you may request to withhold your personal identifying information from public review, we cannot guarantee we will be able to do so.

Teri Barnett,

Departmental Privacy Officer.

SYSTEM NAME AND NUMBER

INTERIOR/DOI–85, Payroll, Attendance, Retirement, and Leave Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

- (1) The INTERIOR/DOI–85, Payroll, Attendance, Retirement, and Leave Records system of records is centrally managed by the Personnel and Payroll Systems Division, Interior Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, MS D–2400, Denver, CO 80235–2230.
- (2) Records are also located at Departmental, bureau and office systems and locations that prepare and provide input documents and information for data processing and administrative actions for this system.

SYSTEM MANAGER(S):

Chief, Personnel and Payroll Systems Division, Interior Business Center, U.S. Department of the Interior, 7301 West Mansfield Avenue, Denver, CO 80235— 2230.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 5101, et seq., Government Organization and Employees; 31 U.S.C. 3512, et seq., Executive Agency Accounting and Other Financial Management Reports and Plans; 31 U.S.C. 1101, et seq., the Budget and Fiscal, Budget, and Program Information; 5 CFR part 293, subpart B, Personnel Records Subject to the Privacy Act; 5 CFR part 297, Privacy Procedures for Personnel Records; Executive Order 9397 as amended by Executive Order 13478, relating to Federal agency use of Social Security numbers; and Public Law 101–576 (Nov. 15, 1990), the Chief Financial Officers (CFO) Act of 1990.

PURPOSE(S) OF THE SYSTEM:

The primary purpose of the system is to manage personnel and payroll functions, to ensure proper payment for salary and benefits, track time and attendance, leave, and other absences for reporting and compliance purposes; and facilitate reporting requirements to other Federal agencies, including the Department of the Treasury and the Office of Personnel Management, for payroll, tax, and human capital management purposes.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by the system include current and former DOI employees, emergency workers, volunteers, contractors, and applicants for Federal employment. This system may also include limited information regarding employee spouses, dependents, emergency contacts, beneficiaries, or estate trustees who meet the definition of "individual" as defined in the Privacy Act.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system maintains records including:

 Employee biographical and employment information: Employee name, other names used, citizenship, gender, date of birth, age, group affiliation, marital status, Social Security number (SSN), truncated SSN, legal status, place of birth, records related to position, occupation, duty location, security clearance, financial information, medical information, disability information, education information, driver's license, race, ethnicity, personal or work telephone number, personal or work email address, military status and service, home or mailing address, Taxpayer Identification Number (TIN), bank account information, professional licensing and credentials, family relationships, involuntary debt (garnishments or child support payments), employee common identifier (ECI), organization code, user identification and any other employment information.

- Third-party information: Spouse information, emergency contact, beneficiary information, savings bond co-owner name(s) and information, and family members and dependents information.
- Salary and benefits information:
 Salary data, retirement data, tax data, deductions, health benefits, allowances, union dues, insurance data, Flexible
 Spending Account, Thrift Savings Plan information and contributions, pay plan, payroll records, awards, court order information, back pay information, debts owed to the government as a result of overpayment, refunds owed, or a debt referred for collection on a transferred employee or emergency worker.
- Timekeeping information: Time and attendance records, and leave records.

This system may also contain correspondence, documents and other information required to administer payroll, leave, and related functions.

RECORD SOURCE CATEGORIES:

Information is obtained from individuals on whom the records are maintained, official personnel records of individuals on whom the records are maintained, supervisors, timekeepers, previous employers, the Internal Revenue Service and state tax agencies, the Department of the Treasury, other Federal agencies, courts, state child support agencies, employing agency accounting offices, and third-party benefit providers.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information maintained in this system may be disclosed to authorized entities outside DOI for purposes determined to be relevant and necessary as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To the Department of Justice (DOJ), including Offices of the U.S. Attorneys, or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when it is relevant or necessary to the litigation and one of the following is a party to the litigation or has an interest in such litigation:

(1) DOI or any component of DOI;

(2) Any other Federal agency appearing before the Office of Hearings and Appeals;

(3) Any DOI employee or former employee acting in his or her official capacity;

(4) Any DOI employee or former employee acting in his or her individual capacity when DOI or DOJ has agreed to represent that employee or pay for private representation of the employee; or

(5) The United States Government or any agency thereof, when DOJ determines that DOI is likely to be

affected by the proceeding.

B. To the Department of the Treasury or other Federal agency as required for payroll purposes, for preparation of payroll and other checks and electronic funds transfers to Federal, State, and local government agencies, non-governmental organizations, and individuals.

C. To the Department of the Treasury, Internal Revenue Service, and state and local tax authorities for which an employee is or was subject to tax regardless of whether tax is or was withheld in accordance with Treasury Fiscal Requirements, as required.

D. To the Office of Personnel Management or its contractors in connection with programs administered by that office, including, but not limited to, the Federal Long Term Care Insurance Program, the Federal Dental and Vision Insurance Program, the Flexible Spending Accounts for Federal Employees Program, and the electronic Human Resources Information Program.

E. To another Federal agency to which an employee or DOI emergency worker has transferred or to which a DOI volunteer transfers in a volunteer

capacity.

F. To any criminal, civil, or regulatory law enforcement authority (whether Federal, state, territorial, local, tribal or foreign) when a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature.

G. To a congressional office in response to a written inquiry that an individual covered by the system, or the heir of such individual if the covered individual is deceased, has made to the

office.

H. To Federal, State or local agencies where necessary to enable the employee's, DOI emergency worker's, or DOI volunteer's agency to obtain information relevant to the hiring or retention of that employee, DOI emergency worker, or DOI volunteer, or the issuance of a security clearance, contract, license, grant or other benefit.

I. To appropriate Federal and state agencies to provide reports including data on unemployment insurance.

J. To the Social Security Administration to credit the employee or emergency worker account for OldAge, Survivors, and Disability Insurance (OASDI) and Medicare deductions.

K. To officials of labor organizations recognized under 5 U.S.C. Chapter 71 (Labor-Management Relations) for the purpose of providing information as to the identity of DOI employees contributing union dues each pay period and the amount of dues withheld from each contributor.

L. To employee or emergency worker associations to report dues deductions.

M. To insurance carriers to report employee or DOI emergency worker election information and withholdings for health insurance.

N. To charitable institutions when an employee designates an institution to receive contributions through salary deduction.

O. To the Department of the Treasury, Internal Revenue Service, or to another Federal agency or its contractor, to disclose debtor information solely to aggregate information for the Internal Revenue Service to collect debts owed to the Federal Government through the offset of tax refunds.

P. To any creditor Federal agency seeking assistance for the purpose of that agency implementing administrative or salary offset procedures in the collection of unpaid financial obligations owed the United States Government from an individual.

Q. To any Federal agency where the individual debtor is employed or receiving some form of remuneration for the purpose of enabling that agency to collect debts on the employee's behalf by administrative or salary offset procedures under the provisions of the Debt Collection Act of 1982.

R. To the Department of the Treasury, Internal Revenue Service, and state and local authorities for the purpose of locating a debtor to collect a claim

against the debtor.

S. With respect to Bureau of Indian Affairs employee or DOI emergency worker records, to a Federal, State, local agency, or Indian tribal group or any establishment or individual that assumes jurisdiction, either by contract or legal transfer, of any program under the control of the Bureau of Indian Affairs.

T. With respect to Bureau of Reclamation employee or DOI emergency worker records, to non-Federal auditors under contract with DOI or the Department of Energy or water user and other organizations with which the Bureau of Reclamation has written agreements permitting access to financial records to perform financial audits.

U. To the Federal Retirement Thrift Investment Board's record keeper, which administers the Thrift Savings Plan, to report deductions, contributions, and loan payments.

V. To the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, for the purposes of locating individuals to establish paternity; establishing and modifying orders of child support; identifying sources of income; and for other child support enforcement actions as required by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

W. To an expert, consultant, grantee, or contractor (including employees of the contractor) of DOI that performs services requiring access to these records on DOI's behalf to carry out the purposes of the system, including employment verifications, unemployment claims, W–2 processing services, leave and earning statements, and 1095–C Affordable Care Act statements.

X. To the Office of Personnel Management Employee Express, which is an employee self-service system, to initiate personnel and payroll actions and to obtain payroll information.

Y. To the Department of Labor for processing claims for employees, emergency workers, or volunteers injured on the job or claiming occupational illness.

Z. To Federal agencies and organizations to support interfaces with other systems operated by the Federal agencies for which the employee or DOI emergency worker is employed, or the DOI volunteer is located, for the purpose of avoiding duplication, increasing data integrity and streamlining government operations.

AA. To another Federal agency to provide information needed in the performance of official duties related to reconciling or reconstructing data files or to enable that agency to respond to an inquiry by the individual to whom the record pertains.

BB. To the National Archives and Records Administration (NARA) to conduct records management inspections under the authority of 44 U.S.C. 2904 and 2906.

CC. To the Office of Management and Budget (OMB) during the coordination and clearance process in connection with legislative affairs as mandated by OMB Circular A–19.

DD. To Federal, state, territorial, local, tribal, or foreign agencies that have requested information relevant or necessary to the hiring, firing or retention of an employee or contractor, regarding the issuance of a security

clearance, license, contract, grant or other benefit.

EE. To state, territorial, and local governments, and tribal organizations to provide information needed in response to court order and/or discovery purposes related to litigation, when the disclosure is compatible with the purpose for which the records were compiled.

FF. To the Department of the Treasury to recover debts owed to the United States.

GG. To the news media and the public, with the approval of the Public Affairs Officer in consultation with counsel and the Senior Agency Official for Privacy, where there exists a legitimate public interest in the disclosure of the information or when disclosure is necessary to preserve confidence in the integrity of DOI or is necessary to demonstrate the accountability of DOI's officers, employees, or individuals covered by the system, except to the extent it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy.

HH. To the Executive Office of the President in response to an inquiry from that office made at the request of the subject of a record or a third party on that person's behalf, or for a purpose compatible with the reason for which the records are collected or maintained.

II. To other Federal agencies and organizations to provide payroll and personnel processing services under a shared service provider cross-servicing agreement for purposes relating to DOI payroll and personnel processing.

JJ. To the Office of Personnel Management, the Merit System Protection Board, Federal Labor Relations Authority, or the Equal Employment Opportunity Commission when requested in the performance of their authorized duties.

KK. To state offices of unemployment compensation to assist in processing an individual's unemployment, survivor annuity, or health benefit claim, or for records reconciliation purposes.

LL. To Federal Employees' Group Life Insurance or Health Benefits carriers in connection with survivor annuity or health benefits claims or records reconciliations.

MM. To any source from which additional information is requested by DOI relevant to a DOI determination concerning an individual's pay, leave, or travel expenses, to the extent necessary to identify the individual, inform the source of the purpose(s) of

the request, and to identify the type of information requested.

NN. To the Social Security Administration and the Department of the Treasury to disclose pay data on an annual basis, and as necessary to execute their statutory responsibilities for the effective administration of benefits programs, payroll and taxes.

OO. To a Federal agency or in response to a congressional inquiry when additional or statistical information is requested relevant to a Federal benefit or program, such as the DOI Transit Fare Subsidy Program.

PP. To the Department of Health and Human Services for the purpose of providing information on new hires and quarterly wages as required under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

QQ. To appropriate agencies, entities,

and persons when:

(1) DOI suspects or has confirmed that there has been a breach of the system of records:

(2) DOI has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOI (including its information systems, programs, and operations), the Federal Government, or national security; and

(3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOI's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

RR. To another Federal agency or Federal entity, when DOI determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in:

(1) Responding to a suspected or confirmed breach; or

(2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

SS. To an agency or organization for the purpose of performing audit or oversight operations as authorized by law, but only such information as is necessary and relevant to such audit or oversight function.

TT. To a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of discovery, pursuant to appropriate court order or other judicial process in the course of criminal, civil or administrative litigation.

UU. In an appropriate proceeding before a court, grand jury, or

administrative or adjudicative body, when the Department of Justice determines that the records are arguably relevant to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosure pursuant to 5 U.S.C. 552a(b)(12). Disclosures may be made from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Act of 1966 (31 U.S.C. 3701(a)(3)).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in manual, microfilm, microfiche, electronic, imaged and computer printout form. Original input documents are stored in standard office filing equipment and/or as imaged documents on magnetic media at all locations which prepare and provide input documents and information for data processing. Paper records are maintained in file folders stored within locking filing cabinets or locked rooms in secured facilities with controlled access. Electronic records are stored in computers, removable drives, storage devices, electronic databases, and other electronic media under the control of DOI.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by employee name, SSN, TIN, ECI, birth date, organizational code, or assigned person number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in accordance with General Records Schedule (GRS) 1.0 "Finance" and GRS 2.0 "Human Resources," and Departmental Records Schedule (DRS) 1.2C, Retirement and Payroll Records Warranting Extended Preservation (DAA-0048-2013-0001-0008), which are approved by NARA. The system generally maintains temporary records, and retention periods vary based on the type of record under each item and the needs of the agency. Paper records are disposed of by shredding or pulping, and records maintained on electronic media are degaussed or erased in accordance with the applicable records retention schedule and NARA guidelines.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

The records maintained in this system are safeguarded in accordance with 43

CFR 2.226 and other applicable security rules and policies. During normal hours of operation, paper or micro format records are maintained in locked file cabinets in secured rooms under the control of authorized personnel. Information technology systems follow the National Institute of Standards and Technology privacy and security standards developed to comply with the Privacy Act of 1974 as amended, 5 U.S.C. 552a; the Paperwork Reduction Act of 1995, Public Law 104-13; the Federal Information Security Modernization Act of 2014, Public Law 113-283, as codified at 44 U.S.C. 3551, et seq.; and the Federal Information Processing Standard 199, Standards for Security Categorization of Federal Information and Information Systems.

Computer servers on which electronic records are stored are located in secured DOI facilities with physical, technical and administrative levels of security to prevent unauthorized access to the DOI network and information assets. Security controls include encryption, firewalls, audit logs, and network system security monitoring. Electronic data is protected through user identification, passwords, database permissions and software controls. Access to records in the system is limited to authorized personnel who have a need to access the records in the performance of their official duties, and each person's access is restricted to only the functions and data necessary to perform that person's job responsibilities. System administrators and authorized users for DOI are trained and required to follow established internal security protocols and must complete all security, privacy, and records management training, and sign DOI Rules of Behavior. A Privacy Impact Assessment was completed for FPPS to ensure that Privacy Act requirements and personally identifiable information safeguard requirements are met, and may be viewed at https://www.doi.gov/privacy/ pia.

RECORD ACCESS PROCEDURES:

An individual requesting records on himself or herself should send a signed, written inquiry to the applicable System Manager identified above. The request must include the requester's bureau and office affiliation to facilitate location of the applicable records. The request envelope and letter should both be clearly marked "PRIVACY ACT REQUEST FOR ACCESS." A request for access must meet the requirements of 43 CFR 2.238.

CONTESTING RECORD PROCEDURES:

An individual requesting corrections or the removal of material from his or her records should send a signed, written request to the applicable System Manager identified above. The request must include the requester's bureau and office affiliation to facilitate location of the applicable records. A request for corrections or removal must meet the requirements of 43 CFR 2.246.

NOTIFICATION PROCEDURES:

An individual requesting notification of the existence of records on himself or herself should send a signed, written inquiry to the applicable System Manager as identified above. The request must include the requester's bureau and office affiliation to facilitate location of the applicable records. The request envelope and letter should both be clearly marked "PRIVACY ACT INQUIRY." A request for notification must meet the requirements of 43 CFR 2.235.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

73 FR 19090 (April 8, 2008). [FR Doc. 2018–15445 Filed 7–18–18; 8:45 am]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X.LLAK930000.L13100000.EI0000.241A]

Call for Nominations and Comments for the National Petroleum Reserve in Alaska 2018 Oil and Gas Lease Sale

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management (BLM) Alaska State Office is issuing a call for nominations and comments on all available tracts for leasing for the upcoming National Petroleum Reserve in Alaska (NPR-A) 2018 Oil and Gas Lease Sale.

DATES: BLM Alaska must receive all nominations and comments on the available tracts for consideration on or before August 20, 2018.

ADDRESSES: Mail nominations and/or comments to: State Director, Bureau of Land Management, Alaska State Office, 222 West 7th Avenue, Mailstop 13, Anchorage, AK 99513–7504.

FOR FURTHER INFORMATION CONTACT: Wayne Svejnoha, BLM Alaska Energy

and Minerals Branch Chief, 907–271–4407. People who use a

telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1-800-877-8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours. SUPPLEMENTARY INFORMATION: The BLM is issuing this call for nominations and comments on tracts available for leasing for the upcoming NPR-A 2018 Oil and Gas Lease Sale, pursuant to 43 CFR 3131.2. To identify tracts you wish to nominate for leasing, or to provide comments, please use the following: (a) NPR-A maps, (b) legal descriptions of the tracts, and (c) any additional information available through the BLM Alaska website at https://www.blm.gov/ programs/energy-and-minerals/oil-andgas/leasing/regional-lease-sales/alaska.

consideration or analysis.

Before including your address, phone number, email address, or other personal identifying information in your nominations and/or comments, please 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 in the body of your comment, we cannot guarantee that we will be able to do so.

The BLM also requests comments on

tracts that should receive special

Authority: 43 CFR 3131.2

Karen E. Mouritsen,

Acting State Director, Alaska. [FR Doc. 2018–15442 Filed 7–18–18; 8:45 am]

BILLING CODE 4310-JA-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLWY922000-L13200000-EL0000, WYW186226]

Notice of Invitation to Participate; Coal Exploration License Application WYW186226, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of invitation.

SUMMARY: Pursuant to the Mineral Leasing Act of 1920, as amended by the Federal Coal Leasing Amendments Act of 1976, and the Bureau of Land Management (BLM) regulations, all interested parties are hereby invited to participate with Black Butte Coal Company on a pro rata cost-sharing basis, in its program for the exploration of coal deposits owned by the United States of America in Sweetwater County, Wyoming.

DATES: This notice of invitation will publish in the *Rock Springs Rocket-Miner* once a week for 2 consecutive weeks beginning the week of March 19, 2018. Any party electing to participate in this exploration program must send written notice to both the BLM and Black Butte Coal Company, as provided in the **ADDRESSES** section below, no later than August 20, 2018.

ADDRESSES: Copies of the exploration plan are available for review during normal business hours in the following offices (serialized under number WYW186226): BLM, Wyoming State Office, 5353 Yellowstone Road. Chevenne, Wyoming 82009; and BLM, Rock Springs Field Office, 280 Highway 191 North, Rock Springs, Wyoming 82901. The written notice should be sent to the following addresses: Black Butte Coal Company, c/o Lighthouse Resources Inc., Attn: Mr. Jason Russell, 10980 South Jordan Gateway, Salt Lake City, UT 84095; and the BLM Wyoming State Office, Branch of Solid Minerals, Attn: Branch Chief, Solid Minerals, P.O. Box 1828, Chevenne, Wyoming 82003.

FOR FURTHER INFORMATION CONTACT: Tim Wilson, Branch Chief, Solid Minerals at 307–775–6179 or tjwilson@blm.gov. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Black Butte Coal Company has applied to the BLM for a 2-year coal exploration license on public land in the Salt Wells area near the existing Black Butte Coal Mine south of Point of Rocks, Wyoming. The purpose of the exploration program is to obtain structural and quality information on the coal. The BLM regulations at 43 CFR 3410.2 require the publication of an invitation for interested parties to participate in the coal exploration in the Federal Register. The Federal coal resources included in the exploration license application are located in the following described lands in Wyoming:

Sixth Principal Meridian, Wyoming
T. 17 N., R. 100 W.,
Secs. 4, 8, 18, and 30.
T. 16 N., R. 101 W.,
Secs. 2, 4, 6, 8, 10, 18, 20, and 30.

T. 17 N., R. 101 W., Sec. 2, lots 1 and 2, $S^{1/2}NE^{1/4}$, $SE^{1/4}NW^{1/4}$, and $S^{1/2}$; Sec. 8:

Sec. 10, E½, and S½SW¼;

Secs. 12, 14, 18, 20, 22, 24, 26, 28, 30, 32, and 34.
T. 15 N., R. 102 W.,

Sec. 4.

T. 16 N., R. 102 W.,

Secs. 2, 10, 12, 14, 22, 24, 26, and 28; Sec. 34, NE $^{1}\!/_{4}$, N $^{1}\!/_{2}$ NW $^{1}\!/_{4}$, SE $^{1}\!/_{4}$ NW $^{1}\!/_{4}$, and S $^{1}\!/_{6}$

T. 17 N., R. 102 W., Secs. 24 and 26.

The areas described aggregate 23.232.28 acres.

The proposed exploration program is fully described and will be conducted pursuant to an exploration plan to be approved by the BLM.

Authority: 43 CFR 3410.2-1(c)(1).

Mary Jo Rugwell,

State Director.

[FR Doc. 2018–15444 Filed 7–18–18; 8:45 am]

BILLING CODE 4310-22-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLORW00000.L10200000. DF0000.18XL1109AF.LXSSH1070000.HAG 18-0120]

Notice of Public Meeting for the John Day—Snake Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) John Day—Snake Resource Advisory Council (JDSRAC) will meet as indicated below. DATES: The JDSRAC will hold a public meeting on Thursday, September 20, 2018, from 12 p.m. to 4:30 p.m. and Friday, September 21, 2018, from 8 a.m. to 12 p.m. A public comment period will be available from 10 a.m. until 10:30 a.m. on September 21, 2018.

ADDRESSES: The JDSRAC meeting will be held at the Malheur National Forest Supervisor's Office at 431 Patterson Bridge Road, John Day, Oregon 97845.

FOR FURTHER INFORMATION CONTACT: Lisa Clark, Public Affairs Officer, 3050 NE 3rd Street, Prineville, Oregon 97754; 541–416–6864; *lmclark@blm.gov*. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–

877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member JDSRAC was chartered to provide information and advice regarding the use and development of the lands administered by the BLM and Forest Service in central and eastern Oregon. Members represent an array of stakeholder interests in the land and resources from within the local area and statewide.

All meetings are open to the public in their entirety. The JDSRAC meeting agenda includes continuing discussion on the Wallowa-Whitman recreation fee proposal and the Lower Deschutes Wild and Scenic River all user fee proposal, as well as a review of the Lower Deschutes Wild and Scenic River draft business plan, and a discussion regarding the shift from seasonal fees to the need for year-round fees at some sites on the Deschutes National Forest. The Malheur National Forest will present the initiation of an Environmental Impact Statement that will analyze the effects of proposed actions to manage wild horses in the joint Forest Service/Prineville BLM Murderers Creek Wild Horse Joint Management Area.

There will be a public comment period from 10 a.m. to 10:30 a.m. on September 21, 2018. Persons wishing to make comments during the public comment period should register in person with the BLM by 8 a.m. on the meeting day, at the meeting location. Depending on the number of persons wishing to comment, the length of comments may be limited. The public may send written comments to the JDSRAC at BLM Prineville District, Attn. Lisa Clark, 3050 NE 3rd Street, Prineville, Oregon 97754. Before including your address, phone number, email address, or other personal identifying information in your comments, please 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 1784.4-2.

Dennis C. Teitzel,

Prineville District Manager.

[FR Doc. 2018-15446 Filed 7-18-18; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[18X LLAK980600.L1820000. XX0000.LXSIARAC0000]

Notice of Public Meeting, BLM Alaska Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Public Meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976, and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Alaska Resource Advisory Council (RAC) will meet as indicated below.

DATES: The BLM Alaska RAC will hold a public meeting Tuesday, August 14, 2018, from 9 a.m. until 4:30 p.m., and Wednesday, August 15, 2018, from 9 a.m. until 4:30 p.m. Public comment periods will be Tuesday from 11:30 a.m. until noon and Wednesday from 3 p.m. until 3:30 p.m.

ADDRESSES: The meeting will take place in Conference Room 104 at the Robert B. Atwood Building, 550 W 7th Ave., Anchorage, Alaska. The meeting agenda will be posted online by August 1, 2018, at www.blm.gov/site-page/get-involved-resource-advisory-council/near-you/alaska/rac.

FOR FURTHER INFORMATION CONTACT:

Lesli Ellis-Wouters, Communications Director, BLM Alaska State Office, 222 W 7th Avenue #13, Anchorage, AK 99513; *lellis@blm.gov*; 907–271–4418. People who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, seven days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member BLM Alaska RAC was chartered to provide advice to the BLM and the Secretary of the Interior on a variety of planning and management issues associated with public land management in Alaska. All RAC meetings are open to the public.

The agenda will include updates on National Environmental Policy Act (NEPA) projects, including the Greater Mooses Tooth 2 Development, proposed Willow Master Development Plan, Red Devil, and the proposed road to the Ambler Mining District. There will be updates on current BLM Alaska planning efforts, such as the Bering Sea-Western Interior and Central Yukon Resource Management Plans, and the Haines and Squirrel River Plans. There will also be reports from RAC subcommittees on placer mining, recreation, trapper cabins, and Alaska Native Claims Settlement Act issues. Discussions will include the BLM's NEPA streamlining and prioritization process, as well as how the BLM works with other federal and state agencies. tribes, and interested parties in preparing NEPA analysis. The three BLM Alaska Districts and the Alaska Fire Service will present overviews of activities occurring in the Field Offices and workload priorities.

During the public comment period, depending upon the number of people wishing to comment, time for individual oral comments may be limited. Please be prepared to submit written comments. If you have information to distribute to the RAC, please do so prior to the start of the meeting.

You can submit written comments by email to *BLM_AK_Communications@ blm.gov*. 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 1784.4-2.

Karen E. Mouritsen,

Acting State Director, Alaska.
[FR Doc. 2018–15447 Filed 7–18–18; 8:45 am]
BILLING CODE 4310–JA–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1369–1372 (Final)]

Fine Denier Polyester Staple Fiber From China, India, Korea, and Taiwan; Determinations

On the basis of the record ¹ developed in the subject investigations, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that an industry in the United States is materially injured by reason of imports of fine denier polyester staple fiber ("fine denier PSF") from China, India, Korea, and Taiwan that have been found by the U.S. Department of Commerce ("Commerce") to be sold in the United States at less than fair value ("LTFV").²³

Background

The Commission, pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)), instituted these investigations effective May 31, 2017, following receipt of a petition filed with the Commission and Commerce by DAK Americas LLC, Charlotte, NC; Nan Ya Plastics Corporation, America, Lake City, SC; and Auriga Polymers Inc., Charlotte, NC. Effective November 6, 2017, the Commission established a general schedule for the conduct of the final phase of its investigations on fine denier PSF, following preliminary determinations by Commerce that imports of the subject fine denier PSF were subsidized by the governments of China and India. Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of November 27, 2017 (82 FR 56050). The hearing was held in Washington, DC, on January 17, 2018,

¹The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

² Fine Denier Polyester Staple Fiber From the People's Republic of China: Final Affirmative Determination of Sales at Less Than Fair Value, 83 FR 24740, May 30, 2018; Fine Denier Polyester Staple Fiber From India: Final Affirmative Determination of Sales at Less Than Fair Value, 83 FR 24737, May 30, 2018; Fine Denier Polyester Staple Fiber From the Republic of Korea: Final Affirmative Determination of Sales at Less Than Fair Value, 83 FR 24743, May 30, 2018; and Fine Denier Polyester Staple Fiber From Taiwan: Final Affirmative Determination of Sales at Less Than Fair Value, 83 FR 24745, May 30, 2018.

³ Commissioner Jason E. Kearns did not participate in these investigations.

and all persons who requested the opportunity were permitted to appear in person or by counsel. Following notification of final determinations by Commerce that imports of fine denier PSF from China, India, Korea, and Taiwan were being sold at LTFV within the meaning of section 735(b) of the Act (19 U.S.C. 1673d(a)), notice of the supplemental scheduling of the final phase of the Commission's antidumping duty investigations was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the Federal Register of June 6, 2018 (83 FR 26308).

The Commission made these determinations pursuant to section 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on July 13, 2018. The views of the Commission are contained in USITC Publication 4803 (July 2018), entitled Fine Denier Polyester Staple Fiber from China, India, Korea, and Taiwan: Investigation Nos. 731–TA–1369–1372 (Final).

By order of the Commission. Issued: July 13, 2018.

Lisa Barton,

Secretary to the Commission. [FR Doc. 2018–15356 Filed 7–18–18; 8:45 am]

BILLING CODE 7020-02-P

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Rules of Criminal Procedure

AGENCY: Judicial Conference of the United States, Advisory Committee on Rules of Criminal Procedure. **ACTION:** Notice of open meeting.

SUMMARY: The Advisory Committee on Rules of Criminal Procedure will hold a meeting on October 10, 2018. The meeting will be open to public observation but not participation. An agenda and supporting materials will be posted at least 7 days in advance of the meeting at: http://www.uscourts.gov/rules-policies/records-and-archives-rules-committees/agenda-books.

DATES: October 10, 2018 from 9:00 a.m. to 5:00 p.m.

ADDRESSES: Vanderbilt University Law School, Alexander Room, 1st Floor, 131 21st Avenue South, Nashville, TN 37203.

FOR FURTHER INFORMATION CONTACT:

Rebecca A. Womeldorf, Rules Committee Secretary, Rules Committee Staff, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 502–1820.

Dated: July 13, 2018.

Rebecca A. Womeldorf,

 $Rules\ Committee\ Secretary.$

[FR Doc. 2018-15360 Filed 7-18-18; 8:45 am]

BILLING CODE 2210-55-P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

TIME AND DATE: 11:00 a.m., Wednesday, July 25, 2018.

PLACE: U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC.

STATUS: Closed. MATTERS TO BE CONSIDERED:

Determination on FIVE original jurisdiction cases.

CONTACT PERSON FOR MORE INFORMATION:

Jacqueline Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC 20530, (202) 346–7001.

Dated: July 16, 2018.

J. Patricia Wilson Smoot,

Chairperson, U.S. Parole Commission. [FR Doc. 2018–15540 Filed 7–17–18; 4:15 pm]

BILLING CODE 4410-31-P

OFFICE OF MANAGEMENT AND BUDGET

Senior Executive Service Performance Review Board Membership

AGENCY: Office of Management and Budget.

ACTION: Notice.

SUMMARY: The Office of Management and Budget (OMB) publishes the names of the members selected to serve on its Senior Executive Service (SES) Performance Review Board (PRB). This notice supersedes all previous notices of the PRB membership.

DATES: Applicable: June 28, 2018.

FOR FURTHER INFORMATION CONTACT:

Sarah Whittle Spooner, Assistant Director for Management and Operations, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503.

SUPPLEMENTARY INFORMATION: Section 4314(c) of Title 5, U.S.C. requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more PRBs. The PRB shall review and evaluate the initial appraisal of a senior

executive's performance by the supervisor, along with any response by the senior executive, and make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on OMB's PRB.

Kelly T. Colyar, Chief, Water and Power Branch

Jennifer L. Hanson, Chief, Income Maintenance Branch

Michael J. Hickey, Chief, Environment Branch

Kirsten J. Moncada, Chief, Privacy Branch

Robert J. Nassif, Chief, Force Structure and Investment Branch

Sarah Whittle Spooner, Assistant Director for Management and Operations

Sarah Spooner,

Assistant Director for Management and Operations.

[FR Doc. 2018–15423 Filed 7–18–18; 8:45 am]

BILLING CODE 3110-01-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2018-044]

Senior Executive Service (SES) Performance Review Board; Members

AGENCY: National Archives and Records Administration.

ACTION: Notice; SES Performance Review Board appointments.

SUMMARY: The National Archives and Records Administration (NARA) is appointing members of NARA's Performance Review Board (PRB). The members of the PRB are: Debra Steidel Wall, Deputy Archivist of the United States; William J. Bosanko, Chief Operating Officer; and Micah M. Cheatham, Chief of Management and Administration. These appointments supersede all previous appointments.

DATES: These appointments are effective on July 19, 2018. **ADDRESSES:** Valorie Findlater, Office of

Human Capital, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT:

Valorie Findlater at 301–837–3754. **SUPPLEMENTARY INFORMATION:** The

authority for this notice is 5 U.S.C. 4314(c), which also requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES Performance Review Boards. The Board shall review the initial appraisal

of a senior executive's performance by the supervisor and recommend final action to the appointing authority regarding matters related to senior executive performance.

David S. Ferriero,

Archivist of the United States.
[FR Doc. 2018–15407 Filed 7–18–18; 8:45 am]
BILLING CODE 7515–01–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Arts and Artifacts Indemnity Panel Advisory Committee

AGENCY: Federal Council on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Federal Council on the Arts and the Humanities will hold a meeting of the Arts and Artifacts Domestic Indemnity Panel.

DATES: The meeting will be held on Wednesday, August 8, 2018, from 12:00 p.m. to 5:00 p.m.

ADDRESSES: The meeting will be held by teleconference originating at the National Endowment for the Arts, Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506, (202) 606–8322; evoyatzis@neh.gov.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is for panel review, discussion, evaluation, and recommendation on applications for Certificates of Indemnity submitted to the Federal Council on the Arts and the Humanities, for exhibitions beginning on or after October 1, 2018. Because the meeting will consider proprietary financial and commercial data provided in confidence by indemnity applicants, and material that is likely to disclose trade secrets or other privileged or confidential information, and because it is important to keep the values of objects to be indemnified, and the methods of transportation and security measures confidential, I have determined that the meeting will be closed to the public pursuant to subsection (c)(4) of section 552b of Title 5, United States Code. I have made this determination under the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated April 15, 2016.

Dated: July 13, 2018.

Elizabeth Vovatzis,

Committee Management Officer, National Endowment for the Humanities.

[FR Doc. 2018–15383 Filed 7–18–18; 8:45 am]

BILLING CODE 7536-01-P

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, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 11a1–1(T); SEC File No. 270–428, OMB Control No. 3235–0478

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 previously approved collection of information provided for in Rule 11a1–1(T) (17 CFR 240.11a1–1(T)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) ("Exchange Act").

On January 27, 1976, the Commission adopted Rule 11a1-1(T) to exempt certain exempt transactions of exchange members for their own accounts that would otherwise be prohibited under Section 11(a) of the Exchange Act. The rule provides that a member's proprietary order may be executed on the exchange of which the trader is a member, if, among other things: (1) The member discloses that a bid or offer for its account is for its account to any member with whom such bid or offer is placed or to whom it is communicated; (2) any such member through whom that bid or offer is communicated discloses to others participating in effecting the order that it is for the account of a member; and (3) immediately before executing the order, a member (other than a specialist in such security) presenting any order for the account of a member on the exchange clearly announces or otherwise indicates to the specialist and to other members then present that he is presenting an order for the account of

Without these requirements, it would not be possible for the Commission to monitor its mandate under the Exchange Act to promote fair and orderly markets and ensure that exchange members have, as the principle purpose of their exchange memberships, the conduct of a public securities business.

There are approximately 592 respondents that require an aggregate total of 17 hours to comply with this rule. Each of these approximately 592 respondents makes an estimated 20 annual responses, for an aggregate of 11,840 responses per year. Each response takes approximately 5 seconds to complete. Thus, the total compliance burden per year is 17 hours $(11,840 \times 5)$ seconds/60 seconds per minute/60 minutes per hour = 17 hours). The approximate internal cost of compliance per hour is \$336, resulting in a total internal cost of compliance for of \$5,712 (17 hours @\$336).

Compliance with Rule 11a–1(T) is necessary for exchange members to make transactions for their own accounts under a specific exemption from the general prohibition of such transactions under Section 11(a) of the Exchange Act. Compliance with Rule 11a–1(T) does not involve the collection of confidential information. Rule 11a–1(T) does not have a record retention requirement per se. However, responses made pursuant to Rule 11a–1(T) may be subject to the recordkeeping requirements of Rules 17a–3 and 17a–4.

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 control number.

The public may view background documentation for this information collection at the following website: 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 Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15376 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83632; File No. SR–NSCC– 2017–017]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Adopt a Recovery and Wind-Down Plan and Related Rules

July 13, 2018.

On December 18, 2017, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–NSCC–2017–017 ("Proposed Rule Change") to adopt a recovery and wind-down plan and related rules.¹ The Proposed Rule

Change was published for comment in the **Federal Register** on January 8. 2018.² On February 8, 2018, the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.³ On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change.⁴ On June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the Proposed Rule Change.⁵ On June 28, 2018, NSCC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.6 As of the date of this release, the Commission has not received any comments on the Proposed Rule Change.

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by NSCC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The Proposed Rule Change proposes to (1) adopt the Recovery & Wind-down Plan of NSCC ("R&W Plan" or "Plan"); and (2) amend NSCC's Rules & Procedures ("Rules") ⁷ in order to adopt Rule 41 (Corporation Default), Rule 42 (Wind-down of the Corporation), and Rule 60 (Market Disruption and Force Majeure) (each a "Proposed Rule" and,

collectively, the "Proposed Rules"). The Proposed Rule Change would also propose to re-number the current Rule 42 (Wind-down of a Member, Fund Member or Insurance Carrier/Retirement Services Member) to Rule 40, which is currently reserved for future use.

The R&W Plan would be maintained by NSCC in compliance with Rule 17Ad-22(e)(3)(ii) under the Act, by providing plans for the recovery and orderly wind-down of NSCC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described below.8 The Proposed Rules are designed to (1) facilitate the implementation of the R&W Plan when necessary and, in particular, allow NSCC to effectuate its strategy for winding down and transferring its business; (2) provide Members and Limited Members with transparency around critical provisions of the R&W Plan that relate to their rights, responsibilities and obligations; and (3) provide NSCC with the legal basis to implement those provisions of the R&W Plan when necessary, as described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of Amendment No. 1

This filing constitutes Amendment No. 1 ("Amendment") to the Proposed Rule Change (also referred to below as the "Original Filing") previously filed by NSCC. 9 NSCC is amending the proposed R&W Plan and the Original Filing in order to clarify certain matters and make minor technical and conforming changes to the R&W Plan, as described below and as marked on Exhibit 4 hereto. To the extent such changes to the Plan require changes to

¹¹⁵ U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively. On December 18, 2017, NSCC filed the Proposed Rule Change as advance notice SR-NSCC-2017-805 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release No. 82581 (January 24, 2018), 83 FR 4327 (January 30, 2018) (SR-NSCC-2017-805). On April 10, 2018, the Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Commission's Request for Additional Information," available at https:// www.sec.gov/rules/sro/nscc-an.htm. On June 28. 2018, NSCC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, NSCC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/nscc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(E) and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at https://www.sec.gov/ rules/sro/nscc-an.htm. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

² Securities Exchange Act Release No. 82430 (January 2, 2018), 83 FR 841 (January 8, 2018) (SR–NSCC–2017–017).

Securities Exchange Act Release No. 82669
 (February 8, 2018), 83 FR 6653 (February 14, 2018)
 (SR-DTC-2017-021; SR-FICC-2017-021; SR-NSCC-2017-017).

⁴ Securities Exchange Act Release No. 82908 (March 20, 2018), 83 FR 12986 (March 26, 2018) (SR-NSCC-2017-017).

⁵ Securities Exchange Act Release No. 83509 (June 25, 2018), 83 FR 30785 (June 29, 2018) (SR–DTC–2017–021; SR–FICC–2017–021; SR–NSCC–2017–017).

⁶To promote the public availability and transparency of its post-notice amendment, NSCC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the Commission's website at https://www.sec.gov/rules/sro/nscc.htm and thus been publicly available since June 29, 2018.

⁷ Capitalized terms used herein and not otherwise defined herein are defined in the Rules, available at www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.

^{8 17} CFR 240.17Ad-22(e)(3)(ii).

⁹ See Securities Exchange Act Release No. 82581 (January 24, 2018), 83 FR 4327 (January 30, 2018) (SR-NSCC-2017-805).

the Original Filing, the information provided under "Description of Proposed Changes" in the Original Filing has been amended and is restated in its entirety below. Other sections of the Original Filing are unchanged and are restated in their entity for convenience.

First, this Amendment would clarify the meaning of the terms "cease to act," "Member default," "Defaulting Member," and "Member Default Losses" as such terms are used in the Plan. This Amendment would also make conforming changes as necessary to reflect the use of these terms.

Second, this Amendment would clarify that actions and tools described in the Plan that are available in one phase of the Crisis Continuum may be used in subsequent phases of the Crisis Continuum when appropriate to address the applicable situation. This Amendment would also clarify that the allocation of losses resulting from a Member default would be applied when provided for, and in accordance with, Rule 4 of the Rules.

Third, this Amendment would clarify that the Recovery Corridor (as defined therein) is not a "sub-phase" of the recovery phase. Rather, the Recovery Corridor is a period of time that would occur toward the end of the Member default phase, when indicators are that NSCC may transition into the recovery phase. Thus, the Recovery Corridor precedes the recovery phase within the Crisis Continuum.

Fourth, this Amendment would make revisions to address the allocation of losses resulting from a Member default in order to more closely conform such statements to the changes proposed by the Loss Allocation Filing, as defined

Fifth, this Amendment would clarify the notifications that NSCC would be required to make under the Proposed Rule 60 (Market Disruption and Force Majeure).

Finally, this Amendment would make minor, technical and conforming revisions to correct typographical errors and to simplify descriptions. For example, such revisions would use lower case for terms that are not defined therein, and would use upper case for terms that are defined. The Amendment would also simplify certain descriptions by removing extraneous words and statements that are repetitive. These minor, technical revisions would not alter the substance of the proposal.

Description of Proposed Changes

NSCC is proposing to adopt the R&W Plan to be used by the Board and management of NSCC in the event

NSCC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would identify (i) the recovery tools available to NSCC to address the risks of (a) uncovered losses or liquidity shortfalls resulting from the default of one or more Members, and (b) losses arising from non-default events, such as damage to its physical assets, a cyber-attack, or custody and investment losses, and (ii) the strategy for implementation of such tools. The R&W Plan would also establish the strategy and framework for the orderly wind-down of NSCC and the transfer of its business in the remote event the implementation of the available recovery tools does not successfully return NSCC to financial viability.

As discussed in greater detail below, the R&W Plan would provide, among other matters, (i) an overview of the business of NSCC and its parent, The Depository Trust & Clearing Corporation ("DTCC"); (ii) an analysis of NSCC's intercompany arrangements and critical links to other financial market infrastructures ("FMIs"); (iii) a description of NSCC's services, and the criteria used to determine which services are considered critical; (iv) a description of the NSCC and DTCC governance structure; (v) a description of the governance around the overall recovery and wind-down program; (vi) a discussion of tools available to NSCC to mitigate credit/market and liquidity risks, including recovery indicators and triggers, and the governance around management of a stress event along a "Crisis Continuum" timeline; (vii) a discussion of potential non-default losses and the resources available to NSCC to address such losses, including recovery triggers and tools to mitigate such losses; (viii) an analysis of the recovery tools' characteristics, including how they are comprehensive, effective, and transparent, how the tools provide appropriate incentives to Members to, among other things, control and monitor the risks they may present to NSCC, and how NSCC seeks to minimize the negative consequences of executing its recovery tools; and (ix) the framework and approach for the orderly winddown and transfer of NSCC's business, including an estimate of the time and costs to effect a recovery or orderly wind-down of NSCC.

The R&W Plan would be structured as a roadmap, and would identify and describe the tools that NSCC may use to effect a recovery from the events and scenarios described therein. Certain recovery tools that would be identified in the R&W Plan are based in the Rules

(including the Proposed Rules) and, as such, descriptions of those tools would include descriptions of, and reference to, the applicable Rules and any related internal policies and procedures. Other recovery tools that would be identified in the R&W Plan are based in contractual arrangements to which NSCC is a party, including, for example, existing committed or pre-arranged liquidity arrangements. Further, the R&W Plan would state that NSCC may develop further supporting internal guidelines and materials that may provide operationally for matters described in the Plan, and that such documents would be supplemental and subordinate to the Plan.

Key factors considered in developing the R&W Plan and the types of tools available to NSCC were its governance structure and the nature of the markets within which NSCC operates. As a result of these considerations, many of the tools available to NSCC that would be described in the R&W Plan are NSCC's existing, business-as-usual risk management and Member default management tools, which would continue to be applied in scenarios of increasing stress. In addition to these existing, business-as-usual tools, the R&W Plan would describe NSCC's other principal recovery tools, which include, for example, (i) identifying, monitoring and managing general business risk and holding sufficient liquid net assets funded by equity ("LNA") to cover potential general business losses pursuant to the Clearing Agency Policy on Capital Requirements ("Capital Policy"),¹⁰ (ii) maintaining the Clearing Agency Capital Replenishment Plan ("Replenishment Plan") as a viable plan for the replenishment of capital should NSCC's equity fall close to or below the amount being held pursuant to the Capital Policy,¹¹ and (iii) the process for the allocation of losses among Members, as provided in Rule 4.12 The R&W Plan

¹⁰ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR– DTC–2017–003, SR–FICC–2017–007, SR–NSCC– 2017-004).

¹¹ See id

¹² See Rule 4 (Clearing Fund), supra note 7. NSCC is proposing changes to Rule 4 and other related rules regarding allocation of losses in a separate filing submitted simultaneously with the Original Filing. See Securities Exchange Act Release Nos. 82430 (January 2, 2018), 83 FR 841 (January 8, 2018) (SR-NSCC-2017-017) and 82581 (January 24, 2018), 83 FR 4327 (January 30, 2018) (SR-NSCC 2017-805) (collectively referred to herein as the "Loss Allocation Filing"). NSCC has submitted an amendment to the Loss Allocation Filing. A copy of the amendment to the Loss Allocation Filing is available at http://www.dtcc.com/legal/sec-rule filings.aspx. NSCC expects the Commission to review both proposals, as amended, together, and, as such, the proposal described in this filing Continued

would provide governance around the selection and implementation of the recovery tool or tools most relevant to mitigate a stress scenario and any applicable loss or liquidity shortfall.

The development of the R&W Plan is facilitated by the Office of Recovery & Resolution Planning ("R&R Team") of DTCC.¹³ The R&R Team reports to the DTCC Management Committee ("Management Committee") and is responsible for maintaining the R&W Plan and for the development and ongoing maintenance of the overall recovery and wind-down planning process. The Board, or such committees as may be delegated authority by the Board from time to time pursuant to its charter, would review and approve the R&W Plan biennially, and would also review and approve any changes that are proposed to the R&W Plan outside of the biennial review.

As discussed in greater detail below, the Proposed Rules would define the procedures that may be employed in the event of NSCC's default and its winddown, and would provide for NSCC's authority to take certain actions on the occurrence of a "Market Disruption Event," as defined therein. Significantly, the Proposed Rules would provide Members and Limited Members with transparency and certainty with respect to these matters. The Proposed Rules would facilitate the implementation of the R&W Plan, particularly NSCC's strategy for winding down and transferring its business, and would provide NSCC with the legal basis to implement those aspects of the R&W Plan.

NSCC R&W Plan

The R&W Plan is intended to be used by the Board and NSCC's management in the event NSCC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be structured to provide a roadmap, define the strategy, and identify the tools available to NSCC to either (i) recover in the event it experiences losses that exceed its prefunded resources (such strategies and tools referred to herein as the "Recovery Plan") or (ii) wind-down its business in a manner designed to permit the continuation of its critical services

in the event that such recovery efforts are not successful (such strategies and tools referred to herein as the "Winddown Plan"). The description of the R&W Plan below is intended to highlight the purpose and expected effects of the material aspects of the R&W Plan, and to provide Members and Limited Members with appropriate transparency into these features.

Business Overview, Critical Services, and Governance

The introduction to the R&W Plan would identify the document's purpose and its regulatory background, and would outline a summary of the Plan. The stated purpose of the R&W Plan is that it is to be used by the Board and NSCC management in the event NSCC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be maintained by NSCC in compliance with Rule 17Åd-22(e)(3)(ii) under the Act 14 by providing plans for the recovery and orderly wind-down of NSCC.

The R&W Plan would describe DTCC's business profile, provide a summary of NSCC's services, and identify the intercompany arrangements and links between NSCC and other entities, including other FMIs. This overview section would provide a context for the R&W Plan by describing NSCC's business, organizational structure and critical links to other entities. By providing this context, this section would facilitate the analysis of the potential impact of utilizing the recovery tools set forth in later sections of the Recovery Plan, and the analysis of the factors that would be addressed in implementing the Wind-down Plan.

DTCC is a user-owned and user-governed holding company and is the parent company of NSCC and its affiliates, The Depository Trust Company ("DTC") and Fixed Income Clearing Corporation ("FICC", and, together with NSCC and DTC, the "Clearing Agencies"). The Plan would describe how corporate support services are provided to NSCC from DTCC and DTCC's other subsidiaries through intercompany agreements under a shared services model.

The Plan would provide a description of established links between NSCC and other FMIs, including The Options Clearing Corporation ("OCC"), CDS Clearing and Depository Services Inc. ("CDS"), and DTC. For example, the arrangement between NSCC and OCC governs the process by which OCC

submits transactions to NSCC for settlement, and sets the time when the settlement obligations and the central counterparty trade guaranty shifts from OCC to NSCC with respect to these transactions. 15 The arrangement with CDS enables participants of CDS to clear and settle OTC trades with U.S. brokerdealers through subaccounts maintained by CDS through its own membership with NSCC.¹⁶ The interface between DTC and NSCC permits transactions to flow between DTC's system and NSCC's Continuous Net Settlement ("CNS") system in a collateralized environment.¹⁷ NSCC's CNS relies on this interface with DTC for the bookentry movement of securities to settle transactions. This section of the Plan, identifying and briefly describing NSCC's established links, would provide a mapping of critical connections and dependencies that may need to be relied on or otherwise addressed in connection with the implementation of either the Recovery Plan or the Wind-down Plan.

The Plan would define the criteria for classifying certain of NSCC's services as "critical," and would identify those critical services and the rationale for their classification. This section would provide an analysis of the potential systemic impact from a service disruption, and is important for evaluating how the recovery tools and the wind-down strategy would facilitate and provide for the continuation of NSCC's critical services to the markets it serves. The criteria that would be used to identify an NSCC service or function as critical would include consideration as to (1) whether there is a lack of alternative providers or products; (2) whether failure of the service could impact NSCC's ability to perform its central counterparty services; (3) whether failure of the service could impact NSCC's ability to perform its netting services, and, as such, the availability of market liquidity; and (4) the service is interconnected with other participants and processes within the U.S. financial system, for example, with other FMIs, settlement banks, broker-dealers, and exchanges. The Plan would then list each of those services, functions or activities that NSCC has identified as

anticipates the approval and implementation of those proposed changes to the Rules.

¹³ DTCC operates on a shared services model with respect to NSCC and its other subsidiaries. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides a relevant service to a subsidiary, including NSCC.

^{14 17} CFR 240.17Ad-22(e)(3)(ii).

 $^{^{15}\,}See$ Securities Exchange Act Release Nos. 81266 (July 31, 2017), 82 FR 36484 (August 4, 2017) (SR–NSCC–2017–007, SR–OCC–2017–013); 81260 (July 31, 2017), 82 FR 36476 (August 4, 2017) (SR–NSCC–2017–803, SR–OCC–2017–804); Procedure III (Trade Recording Service (Interface with Qualified Clearing Agencies)), supra note 7.

¹⁶ See Rule 61 (International Links), supra note 7.

¹⁷ See Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation), supra note 7.

"critical" based on the applicability of these four criteria. Such critical services would include, for example, trade capture and recording through the Universal Trade Capture system, 18 services supporting Correspondent Clearing relationships, 19 the CNS system, 20 the Balance Order Netting system, 21 Mutual Funds Services, 22 and the settlement of money payments with respect to transactions processed by NSCC. 23 The R&W Plan would also include a non-exhaustive list of NSCC services that are not deemed critical.

The evaluation of which services provided by NSCC are deemed critical is important for purposes of determining how the R&W Plan would facilitate the continuity of those services. As discussed further below, while NSCC's Wind-down Plan would provide for the transfer of all critical services to a transferee in the event NSCC's winddown is implemented, it would anticipate that any non-critical services that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership, would also be transferred.

The Plan would describe the governance structure of both DTCC and NSCC. This section of the Plan would identify the ownership and governance model of these entities at both the Board of Directors and management levels. The Plan would state that the stages of escalation required to manage recovery under the Recovery Plan or to invoke NSCC's wind-down under the Winddown Plan would range from relevant business line managers up to the Board through NSCC's governance structure. The Plan would then identify the parties responsible for certain activities under both the Recovery Plan and the Winddown Plan, and would describe their respective roles. The Plan would identify the Risk Committee of the Board ("Board Risk Committee") as being responsible for oversight of risk management activities at NSCC, which include focusing on both oversight of risk management systems and processes designed to identify and manage various risks faced by NSCC, and, due to

NSCC's critical role in the markets in which it operates, oversight of NSCC's efforts to mitigate systemic risks that could impact those markets and the broader financial system.²⁴ The Plan would identify the DTCC Management Risk Committee ("Management Risk Committee") as primarily responsible for general, day-to-day risk management through delegated authority from the Board Risk Committee. The Plan would state that the Management Risk Committee has delegated specific dayto-day risk management, including management of risks addressed through margining systems and related activities, to the DTCC Group Chief Risk Office ("GCRO"), which works with staff within the DTCC Financial Risk Management group. Finally, the Plan would describe the role of the Management Committee, which provides overall direction for all aspects of NSCC's business, technology, and operations and the functional areas that support these activities.

The Plan would describe the governance of recovery efforts in response to both default losses and nondefault losses under the Recovery Plan, identifying the groups responsible for those recovery efforts. Specifically, the Plan would state that the Management Risk Committee provides oversight of actions relating to the default of a Member, which would be reported and escalated to it through the GCRO, and the Management Committee provides oversight of actions relating to nondefault events that could result in a loss, which would be reported and escalated to it from the DTCC Chief Financial Officer ("CFO") and the DTCC Treasury group that reports to the CFO, and from other relevant subject matter experts based on the nature and circumstances of the non-default event.25 More generally, the Plan would state that the type of loss and the nature and circumstances of the events that lead to the loss would dictate the components of governance to address that loss, including the escalation path to authorize those actions. As described

further below, both the Recovery Plan and the Wind-down Plan would describe the governance of escalations, decisions, and actions under each of those plans.

Finally, the Plan would describe the role of the R&R Team in managing the overall recovery and wind-down program and plans for each of the Clearing Agencies.

NSCC Recovery Plan

The Recovery Plan is intended to be a roadmap of those actions that NSCC may employ to monitor and, as needed, stabilize its financial condition. As each event that could lead to a financial loss could be unique in its circumstances, the Recovery Plan would not be prescriptive and would permit NSCC to maintain flexibility in its use of identified tools and in the sequence in which such tools are used, subject to any conditions in the Rules or the contractual arrangement on which such tool is based. NSCC's Recovery Plan would consist of (1) a description of the risk management surveillance, tools, and governance that NSCC would employ across evolving stress scenarios that it may face as it transitions through a "Crisis Continuum," described below; (2) a description of NSCC's risk of losses that may result from non-default events. and the financial resources and recovery tools available to NSCC to manage those risks and any resulting losses; and (3) an evaluation of the characteristics of the recovery tools that may be used in response to either default losses or nondefault losses, as described in greater detail below. In all cases, NSCC would act in accordance with the Rules, within the governance structure described in the R&W Plan, and in accordance with applicable regulatory oversight to address each situation in order to best protect NSCC, Members, and the markets in which it operates.

Managing Member Default Losses and Liquidity Needs Through the Crisis Continuum. The Recovery Plan would describe the risk management surveillance, tools, and governance that NSCC may employ across an increasing stress environment, which is referred to as the "Crisis Continuum." This description would identify those tools that can be employed to mitigate losses, and mitigate or minimize liquidity needs, as the market environment becomes increasingly stressed. The phases of the Crisis Continuum would include (1) a stable market phase, (2) a stress market phase, (3) a phase commencing with NSCC's decision to cease to act for a Member or Affiliated Family of Members (referred to in the

¹⁸ See Rule 7 (Comparison and Trade Recording Operation) and Procedure II (Trade Comparison and Recording Service), *supra* note 7.

¹⁹ See Procedure IV (Special Representative Service), supra note 7.

 $^{^{20}\,}See$ Rule 11 (CNS System) and Procedure VII (CNS Accounting Operation), supra note 7.

 $^{^{21}}$ See Rule 8 (Balance Order and Foreign Security Systems) and Procedure V (Balance Order Accounting Operation), supra note 7.

²² See Rule 52 (Mutual Funds Services), supra note 7.

 $^{^{23}}$ See Rule 12 (Settlement) and Procedure VIII (Money Settlement Service), supra note 7.

²⁴ The charter of the Board Risk Committee is available at http://www.dtc.com/~/media/Files/ Downloads/legal/policy-and-compliance/DTCC-BOD-Risk-Committee-Charter.pdf.

²⁵ The Plan would state that these groups would be involved to address how to mitigate the financial impact of non-default losses, and in recommending mitigating actions, the Management Committee would consider information and recommendations from relevant subject matter experts based on the nature and circumstances of the non-default event. Any necessary operational response to these events, however, would be managed in accordance with applicable incident response/business continuity process; for example, processes established by the DTCC Technology Risk Management group would be followed in response to a cyber event.

Plan as the "Member default phase"),26 and (4) a recovery phase. This section of the Recovery Plan would address conditions and circumstances relating to NSCC's decision to cease to act for a Member pursuant to the Rules.²⁷ In the Plan, "cease to act" and the events that may lead to such decision, are used within the context of Rule 46 of the Rules.²⁸ Further, for ease of reference, the R&W Plan would, for purposes of the Plan, use the term "Member default" to refer to the event or events that precipitate NSCC ceasing to act for a Member or an Affiliated Family, would use the term "Defaulting Member" to refer to a Member for which NSCC has ceased to act, and would use the term "Member Default Losses" to refer to losses that arise out of or relate to the Member default (including any losses that arise from liquidation of that Member's portfolio), and to distinguish such losses from those that arise out of the business or other events not related to a Member default, which are separately addressed in the Plan.

The Recovery Plan would provide context to its roadmap through this Crisis Continuum by describing NSCC's ongoing management of credit, market and liquidity risk, and its existing process for measuring and reporting its risks as they align with established thresholds for its tolerance of those risks. The Recovery Plan would discuss the management of credit/market risk and liquidity exposures together, because the tools that address these risks can be deployed either separately or in a coordinated approach in order to address both exposures. NSCC manages these risk exposures collectively to limit their overall impact on NSCC and its membership. As part of its market risk management strategy, NSCC manages its credit exposure to Members by determining the appropriate Required Deposits to the Clearing Fund and monitoring its sufficiency, as provided for in the Rules.29 NSCC manages its

liquidity risks with an objective of maintaining sufficient resources to be able to fulfill obligations that have been guaranteed by NSCC in the event of a Member default that presents the largest aggregate liquidity exposure to NSCC over the settlement cycle.30

The Recovery Plan would outline the metrics and indicators that NSCC has developed to evaluate a stress situation against established risk tolerance thresholds. Each risk mitigation tool identified in the Recovery Plan would include a description of the escalation thresholds that allow for effective and timely reporting to the appropriate internal management staff and committees, or to the Board. The Recovery Plan would make clear that these tools and escalation protocols would be calibrated across each phase of the Crisis Continuum. The Recovery Plan would also establish that NSCC would retain the flexibility to deploy such tools either separately or in a coordinated approach, and to use other alternatives to these actions and tools as necessitated by the circumstances of a particular Member default, in accordance with the Rules. Therefore, the Recovery Plan would both provide NSCC with a roadmap to follow within each phase of the Crisis Continuum, and would permit it to adjust its risk management measures to address the unique circumstances of each event.

The Recovery Plan would describe the conditions that mark each phase of the Crisis Continuum, and would identify actions that NSCC could take as it transitions through each phase in order to both prevent losses from materializing through active risk management, and to restore the financial health of NSCC during a period of stress.

The stable market phase of the Crisis Continuum would describe active risk management activities in the normal course of business. These activities would include (1) routine monitoring of margin adequacy through daily review of back testing and stress testing results that review the adequacy of NSCC's margin calculations, and escalation of those results to internal and Board

committees; 31 and (2) routine monitoring of liquidity adequacy through review of daily liquidity studies that measure sufficiency of available liquidity resources to meet cash settlement obligations of the Member that would generate the largest aggregate payment obligation.32

The Recovery Plan would describe some of the indicators of the stress market phase of the Crisis Continuum, which would include, for example, volatility in market prices of certain assets where there is increased uncertainty among market participants about the fundamental value of those assets. This phase would involve general market stresses, when no Member default would be imminent. Within the description of this phase, the Recovery Plan would provide that NSCC may take targeted, routine risk management measures as necessary and

as permitted by the Rules.

Within the Member default phase of the Crisis Continuum, the Recovery Plan would provide a roadmap for the existing procedures that NSCC would follow in the event of a Member default and any decision by NSCC to cease to act for that Member.³³ The Recovery Plan would provide that the objectives of NSCC's actions upon a Member or Affiliated Family default are to (1) minimize losses and market exposure of the affected Members and NSCC's non-Defaulting Members; and (2), to the extent practicable, minimize disturbances to the affected markets. The Recovery Plan would describe tools, actions, and related governance for both market risk monitoring and liquidity risk monitoring through this phase. For example, in connection with managing its market risk during this phase, NSCC would, pursuant to the Rules, (1) monitor and assess the adequacy of Clearing Fund resources; (2), when necessary and appropriate pursuant to the Rules, assess and collect additional margin requirements; and (3) follow its operational procedures to liquidate the Defaulting Member's portfolio. Management of liquidity risk through this phase would involve ongoing monitoring of the adequacy of NSCC's liquidity resources, and the Recovery Plan would identify certain

²⁶ The Plan would define an "Affiliated Family" of Members as a number of affiliated entities that are all Members of NSCC

²⁷ See Rule 46 (Restrictions on Access to Services), supra note 7.

 $^{^{29}\,}See$ Rule 4 (Clearing Fund) and Procedure XV (Clearing Fund Formula and Other Matters), supra note 7. Because NSCC does not maintain a guaranty fund separate and apart from the Clearing Fund it collects from Members, NSCC monitors its credit exposure to its Members by managing the market risks of each Member's unsettled portfolio through the collection of the Clearing Fund. The aggregate of all Members' Required Fund Deposits comprises the Clearing Fund that represents NSCC's prefunded resources to address uncovered loss exposures, as provided for in proposed Rule 4. Therefore, NSCC's market risk management strategy is designed to comply with Rule 17Ad-22(e)(4)

under the Act, where these risks are referred to as 'credit risks." See also 17 CFR 240.17Ad-22(e)(4).

³⁰ NSCC's liquidity risk management strategy, including the manner in which NSCC utilizes its liquidity tools, is described in the Clearing Agency Liquidity Risk Management Framework. See Securities Exchange Act Release Nos. 80489 (April 19, 2017), 82 FR 19120 (April 25, 2017) (SR-DTC-2017-004, SR-NSCC-2017-005, SR-FICC-2017-008); 81194 (July 24, 2017), 82 FR 35241 (July 28, 2017) (SR-DTC-2017-004, SR-NSCC-2017-005, SR-FICC-2017-008).

³¹NSCC's stress testing practices are described in the Clearing Agency Stress Testing Framework (Market Risk). See Securities Exchange Act Release Nos. 80485 (April 19, 2017), 82 FR 19131 (April 25, 2017) (SR-DTC-2017-005, SR-FICC-2017-009, SR-NSCC-2017-006); 81192 (July 24, 2017), 82 FR 35245 (July 28, 2017) (SR-DTC-2017-005, SR-FICC-2017-009, SR-NSCC-2017-006).

³² See supra note 30.

 $^{^{33}}$ See Rule 18 (Procedures for When the Corporation Declines or Ceases to Act) and Rule 46 (Restrictions on Access to Services), supra note 7.

actions NSCC may deploy as it deems necessary to mitigate a potential liquidity shortfall, which would include, for example, adjusting its strategy for closing out the Defaulting Member's portfolio or seeking additional liquidity resources. The Recovery Plan would state that, throughout this phase, relevant information would be escalated and reported to both internal management committees and the Board Risk Committee.

The Recovery Plan would also identify financial resources available to NSCC, pursuant to the Rules, to address losses arising out of a Member default. Specifically, Rule 4, as proposed to be amended by the Loss Allocation Filing, would provide that losses remaining after application of the Defaulting Member's resources be satisfied first by applying a "Corporate Contribution," and then, if necessary, by allocating remaining losses among the membership in accordance with such Rule 4.34

In order to provide for an effective and timely recovery, the Recovery Plan would describe the period of time that would occur near the end of the Member default phase, during which NSCC may experience stress events or observe early warning indicators that allow it to evaluate its options and prepare for the recovery phase (referred to in the Plan as the "Recovery Corridor"). The Recovery Plan would then describe the recovery phase of the Crisis Continuum, which would begin on the date that NSCC issues the first Loss Allocation Notice of the second loss allocation round with respect to a given "Event Period." 35 The recovery

phase would describe actions that NSCC may take to avoid entering into a wind down of its business.

NSCC expects that significant deterioration of liquidity resources would cause it to enter the Recovery Corridor. As such, the Plan would describe the actions NSCC may take aimed at replenishing those resources. Recovery Corridor indicators may include, for example, a rapid and material change in market prices or substantial intraday activity volume by the Member that subsequently defaults, neither of which are mitigated by intraday margin calls, or subsequent defaults by other Members or Affiliated Families during a compressed time period. Throughout the Recovery Corridor, NSCC would monitor the adequacy of its resources and the expected timing of replenishment of those resources, and would do so through the monitoring of certain corridor indicator metrics.

The majority of the corridor indicators, as identified in the Recovery Plan, relate directly to conditions that may require NSCC to adjust its strategy for hedging and liquidating a Defaulting Member's portfolio, and any such changes would include an assessment of the status of the corridor indicators. Corridor indicators would include, for example, effectiveness and speed of NSCC's efforts to close out the portfolio of the Defaulting Member, and an impediment to the availability of its financial resources. For each corridor indicator, the Recovery Plan would identify (1) measures of the indicator, (2) evaluations of the status of the indicator, (3) metrics for determining the status of the deterioration or improvement of the indicator, and (4) "Corridor Actions," which are steps that may be taken to improve the status of the indicator, 36 as well as management escalations required to authorize those steps. Because NSCC has never experienced the default of multiple Members, it has not, historically, measured the deterioration or improvements metrics of the corridor indicators. As such, these metrics were

chosen based on the business judgment of NSCC management.

The Recovery Plan would also describe the reporting and escalation of the status of the corridor indicators throughout the Recovery Corridor. Significant deterioration of a corridor indicator, as measured by the metrics set out in the Recovery Plan, would be escalated to the Board. NSCC management would review the corridor indicators and the related metrics at least annually, and would modify these metrics as necessary in light of observations from simulations of Member defaults and other analyses. Any proposed modifications would be reviewed by the Management Risk Committee and the Board Risk Committee. The Recovery Plan would estimate that NSCC may remain in the Recovery Corridor between one day and two weeks. This estimate is based on historical data observed in past Member defaults, the results of simulations of Member defaults, and periodic liquidity analyses conducted by NSCC. The actual length of a Recovery Corridor would vary based on actual market conditions observed at the time, and NSCC would expect the Recovery Corridor to be shorter in market conditions of increased stress.

The Recovery Plan would outline steps by which NSCC may allocate its losses, which would occur when and in the order provided in Rule 4, as amended.37 The Recovery Plan would also identify tools that may be used to address foreseeable shortfalls of NSCC's liquidity resources following a Member default, and would provide that these tools may be used as appropriate during the Crisis Continuum to address liquidity shortfalls if they arise. The goal in managing NSCC's qualified liquidity resources is to maximize resource availability in an evolving stress situation, to maintain flexibility in the order and use of sources of liquidity, and to repay any third party lenders of liquidity in a timely manner. These liquidity tools include, for example, NSCC's committed 364-day credit facility,38 and the issuance and private placement of additional shortterm promissory notes ("commercial paper") and extendible notes, the cash proceeds of which provide NSCC with

³⁴ See supra note 12. The Loss Allocation Filing proposes to amend Rule 4 to define the amount NSCC would contribute to address a loss resulting from either a Member default or a non-default event as the "Corporate Contribution." This amount would be 50 percent (50%) of the "General Business Risk Capital Requirement," which is calculated pursuant to the Capital Policy and is an amount sufficient to cover potential general business losses so that NSCC can continue operations and services as a going concern if those losses materialize, in compliance with Rule 17Ad–22(e)(15) under the Act. See also supra note 10; 17 CFR 240.17Ad–22(e)(15).

³⁵ The Loss Allocation Filing proposes to amend Rule 4 to introduce the concept of an "Event Period" as the ten (10) Business Days beginning on (i) with respect to a Member default, the day on which NSCC notifies Members that it has ceased to act for a Member under the Rules, or (ii) with respect to a non-default loss, the day that NSCC notifies Members of the determination by the Board that there is a non-default loss event, as described in greater detail in that filing. The proposed Rule 4 would define a "round" as a series of loss allocations relating to an Event Period, and would provide that the first Loss Allocation Notice in a first, second, or subsequent round shall expressly state that such notice reflects the beginning of a

first, second, or subsequent round. The maximum allocable loss amount of a round is equal to the sum of the "Loss Allocation Caps" (as defined in the proposed Rule 4) of those Members included in the round. See supra note 12.

³⁶ The Corridor Actions that would be identified in the Plan are indicative, but not prescriptive; therefore, if NSCC needs to consider alternative actions due to the applicable facts and circumstances, the escalation of those alternative actions would follow the same escalation protocol identified in the Plan for the Corridor Indicator to which the action relates.

³⁷ As these matters are described in greater detail in the Loss Allocation Filing and in the proposed amendments to Rule 4, described therein, reference is made to that filing and the details are not repeated here. See supra note 12.

³⁸ See Securities Exchange Act Release No. 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR–DTC–2017–802, SR–NSCC–2017–802).

prefunded liquidity.³⁹ Additional voluntary or uncommitted tools to address potential liquidity shortfalls, for example uncommitted bank loans, which may supplement NSCC's other liquid resources described herein, would also be identified in the Recovery Plan. The Recovery Plan would state that, due to the extreme nature of a stress event that would cause NSCC to consider the use of these liquidity tools, the availability and capacity of these liquidity tools, and the willingness of counterparties to lend, cannot be accurately predicted and are dependent on the circumstances of the applicable stress period, including market price volatility, actual or perceived disruptions in financial markets, the costs to NSCC of utilizing these tools, and any potential impact on NSCC's credit rating.

As stated above, the Recovery Plan would state that NSCC will have entered the recovery phase on the date that it issues the first Loss Allocation Notice of the second loss allocation round with respect to a given Event Period. The Recovery Plan would provide that, during the recovery phase, NSCC would continue and, as needed, enhance, the monitoring and remedial actions already described in connection with previous phases of the Crisis Continuum, and would remain in the recovery phase until its financial resources are expected to be or are fully replenished, or until the Wind-down Plan is triggered, as described below.

The Recovery Plan would describe governance for the actions and tools that may be employed within each phase of the Crisis Continuum, which would be dictated by the facts and circumstances applicable to the situation being addressed. Such facts and circumstances would be measured by the various indicators and metrics applicable to that phase of the Crisis Continuum, and would follow the relevant escalation protocols that would be described in the Recovery Plan. The Recovery Plan would also describe the governance procedures around a decision to cease to act for a Member, pursuant to the Rules, and around the management and oversight of the subsequent liquidation of the Defaulting Member's portfolio. The Recovery Plan would state that, overall, NSCC would retain flexibility in accordance with the Rules, its governance structure, and its regulatory oversight, to address a particular situation in order to best protect NSCC and the Members, and to

meet the primary objectives, throughout the Crisis Continuum, of minimizing losses and, where consistent and practicable, minimizing disturbance to affected markets.

Non-Default Losses. The Recovery Plan would outline how NSCC may address losses that result from events other than a Member default. While these matters are addressed in greater detail in other documents, this section of the Plan would provide a roadmap to those documents and an outline for NSCC's approach to monitoring and managing losses that could result from a non-default event. The Plan would first identify some of the risks NSCC faces that could lead to these losses, which include, for example, the business and profit/loss risks of unexpected declines in revenue or growth of expenses; the operational risks of disruptions to systems or processes that could lead to large losses. including those resulting from, for example, a cyber-attack; and custody or investment risks that could lead to financial losses. The Recovery Plan would describe NSCC's overall strategy for the management of these risks, which includes a "three lines of defense" approach to risk management that allows for comprehensive management of risk across the organization.⁴⁰ The Recovery Plan would also describe NSCC's approach to financial risk and capital management. The Plan would identify key aspects of this approach, including, for example, an annual budget process, business line performance reviews with management, and regular review of capital requirements against LNA. These risk management strategies are collectively intended to allow NSCC to effectively

identify, monitor, and manage risks of non-default losses.

The Plan would identify the two categories of financial resources NSCC maintains to cover losses and expenses arising from non-default risks or events as (1) LNA, maintained, monitored, and managed pursuant to the Capital Policy, which include (a) amounts held in satisfaction of the General Business Risk Capital Requirement,⁴¹ (b) the Corporate Contribution,⁴² and (c) other amounts held in excess of NSCC's capital requirements pursuant to the Capital Policy; and (2) resources available pursuant to the loss allocation provisions of Rule 4.⁴³

The Plan would address the process by which the CFO and the DTCC Treasury group would determine which available LNA resources are most appropriate to cover a loss that is caused by a non-default event. This determination involves an evaluation of a number of factors, including the current and expected size of the loss, the expected time horizon over when the loss or additional expenses would materialize, the current and projected available LNA, and the likelihood LNA could be successfully replenished pursuant to the Replenishment Plan, if triggered.44 Finally the Plan would discuss how NSCC would apply its resources to address losses resulting from a non-default event, including the order of resources it would apply if the loss or liability exceeds NSCC's excess LNA amounts, or is large relative thereto, and the Board has declared the event a "Declared Non-Default Loss Event" pursuant to Rule 4.45

The Plan would also describe proposed Rule 60 (Market Disruption and Force Majeure), which NSCC is proposing to adopt in the Rules. This Proposed Rule would provide transparency around how NSCC would address extraordinary events that may occur outside its control. Specifically, the Proposed Rule would define a "Market Disruption Event" and the governance around a determination that such an event has occurred. The Proposed Rule would also describe NSCC's authority to take actions during the pendency of a Market Disruption Event that it deems appropriate to address such an event and facilitate the continuation of its services, if practicable, as described in greater detail below.

³⁹ See Securities Exchange Act Release No. 75730 (August 19, 2015), 80 FR 51638 (August 25, 2015) (SR-NSCC-2015-802).

 $^{^{\}rm 40}\,\rm This$ "three lines of defense" approach to risk management includes (1) a first line of defense comprised of the various business lines and functional units that support the products and services offered by NSCC; (2) a second line of defense comprised of control functions that support NSCC, including the risk management, legal and compliance areas; and (3) a third line of defense, which is performed by an internal audit group. The Clearing Agency Risk Management Framework includes a description of this "three lines of defense" approach to risk management, and addresses how NSCC comprehensively manages various risks, including operational, general business, investment, custody, and other risks that arise in or are borne by it. See Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR-DTC-2017-013, SR-FICC-2017-016, SR-NSCC-2017-012). The Clearing Agency Operational Risk Management Framework describes the manner in which NSCC manages operational risks, as defined therein. See Securities Exchange Act Release No. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR-DTC-2017-014, SR-FICC-2017-017, SR-NSCC-2017-013).

⁴¹ See supra note 34.

⁴² See supra note 34.

⁴³ See supra note 12.

⁴⁴ See supra note 10.

⁴⁵ See supra note 12.

The Plan would describe the interaction between the Proposed Rule and NSCC's existing processes and procedures addressing business continuity management and disaster recovery (generally, the "BCM/DR procedures"), making clear that the Proposed Rule is designed to support those BCM/DR procedures and to address circumstances that may be exogenous to NSCC and not necessarily addressed by the BCM/DR procedures. Finally, the Plan would describe that, because the operation of the Proposed Rule is specific to each applicable Market Disruption Event, the Proposed Rule does not define a time limit on its application. However, the Plan would note that actions authorized by the Proposed Rule would be limited to the pendency of the applicable Market Disruption Event, as made clear in the Proposed Rule. Overall, the Proposed Rule is designed to mitigate risks caused by Market Disruption Events and, thereby, minimize the risk of financial loss that may result from such events.

Recovery Tool Characteristics. The Recovery Plan would describe NSCC's evaluation of the tools identified within the Recovery Plan, and its rationale for concluding that such tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to Members and minimize negative impact on Members and the financial system, in compliance with guidance published by the Commission in connection with the adoption of Rule 17Ad-22(e)(3)(ii) under the Act. 46 NSCC's analysis and the conclusions set forth in this section of the Recovery Plan are described in greater detail in Item 3(b) of this filing, below.

NSCC Wind-Down Plan

The Wind-down Plan would provide the framework and strategy for the orderly wind-down of NSCC if the use of the recovery tools described in the Recovery Plan do not successfully return NSCC to financial viability. While NSCC believes that, given the comprehensive nature of the recovery tools, such event is extremely unlikely, as described in greater detail below, NSCC is proposing a wind-down strategy that provides for (1) the transfer of NSCC's business, assets and membership to another legal entity, (2) such transfer being effected in connection with proceedings under Chapter 11 of the U.S. Federal

Bankruptcy Code,⁴⁷ and (3) after effectuating this transfer, NSCC liquidating any remaining assets in an orderly manner in bankruptcy proceedings. NSCC believes that the proposed transfer approach to a winddown would meet its objectives of (1) assuring that NSCC's critical services will be available to the market as long as there are Members in good standing, and (2) minimizing disruption to the operations of Members and financial markets generally that might be caused by NSCC's failure.

In describing the transfer approach to NSCC's Wind-down Plan, the Plan would identify the factors that NSCC considered in developing this approach, including the fact that NSCC does not own material assets that are unrelated to its clearance and settlement activities. As such, a business reorganization or "bail-in" of debt approach would be unlikely to mitigate significant losses. Additionally, NSCC's approach was developed in consideration of its critical and unique position in the U.S. markets, which precludes any approach that would cause NSCC's critical services to no longer be available.

First, the Wind-down Plan would describe the potential scenarios that could lead to the wind-down of NSCC, and the likelihood of such scenarios. The Wind-down Plan would identify the time period leading up to a decision to wind-down NSCC as the "Runway Period." This period would follow the implementation of any recovery tools, as it may take a period of time, depending on the severity of the market stress at that time, for these tools to be effective or for NSCC to realize a loss sufficient to cause it to be unable to effectuate settlements and repay its obligations.48 The Wind-down Plan would identify some of the indicators that it has entered this Runway Period, which would include, for example, successive Member defaults, significant Member retirements thereafter, and NSCC's inability to replenish its financial resources following the liquidation of the portfolio of the Defaulting Member(s).

The trigger for implementing the Wind-down Plan would be a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning

NSCC to viability as a going concern. As described in the Plan, NSCC believes this is an appropriate trigger because it is both broad and flexible enough to cover a variety of scenarios, and would align incentives of NSCC and the Members to avoid actions that might undermine NSCC's recovery efforts. Additionally, this approach takes into account the characteristics of NSCC's recovery tools and enables the Board to consider (1) the presence of indicators of a successful or unsuccessful recovery, and (2) potential for knock-on effects of continued iterative application of NSCC's recovery tools.

The Wind-down Plan would describe the general objectives of the transfer strategy, and would address assumptions regarding the transfer of NSCC's critical services, business, assets and membership, and the assignment of NSCC's links with other FMIs, to another legal entity that is legally, financially, and operationally able to provide NSCC's critical services to entities that wish to continue their membership following the transfer ("Transferee"). The Wind-down Plan would provide that the Transferee would be either (1) a third party legal entity, which may be an existing or newly established legal entity or a bridge entity formed to operate the business on an interim basis to enable the business to be transferred subsequently ("Third Party Transferee"); or (2) an existing, debt-free failover legal entity established ex-ante by DTCC ("Failover Transferee") to be used as an alternative Transferee in the event that no viable or preferable Third Party Transferee timely commits to acquire NSCC's business. NSCC would seek to identify the proposed Transferee, and negotiate and enter into transfer arrangements during the Runway Period and prior to making any filings under Chapter 11 of the U.S. Federal Bankruptcy Code. 49 As stated above, the Wind-down Plan would anticipate that the transfer to the Transferee be effected in connection with proceedings under Chapter 11 of the U.S. Federal Bankruptcy Code, and pursuant to a bankruptcy court order under Section 363 of the Bankruptcy Code, such that the transfer would be free and clear of claims against, and interests in, NSCC, except to the extent expressly provided in the court's ${
m order.}^{50}$

In order to effect a timely transfer of its services and minimize the market and operational disruption of such transfer, NSCC would expect to transfer

⁴⁶ Standards for Covered Clearing Agencies, Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14).

⁴⁷ 11 U.S.C. 1101 et seq.

⁴⁸The Wind-down Plan would state that, given NSCC's position as a user-governed financial market utility, it is possible that Members might voluntarily elect to provide additional support during the recovery phase leading up to a potential trigger of the Wind-down Plan, but would also make clear that NSCC cannot predict the willingness of Members to do so.

⁴⁹ See 11 U.S.C. 1101 et seq.

⁵⁰ See id. at 363.

all of its critical services and any noncritical services that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership. Following the transfer, the Wind-down Plan would anticipate that the Transferee and its continuing membership would determine whether to continue to provide any transferred non-critical service on an ongoing basis, or terminate the non-critical service following some transition period. NSCC's Wind-down Plan would anticipate that the Transferee would enter into a transition services agreement with DTCC so that DTCC would continue to provide the shared services it currently provides to NSCC, including staffing, infrastructure and operational support. The Wind-down Plan would also anticipate the assignment of NSCC's link arrangements, including those with DTC, CDS and OCC, described above, to the Transferee.⁵¹ The Wind-down Plan would provide that Members' open positions existing prior to the effective time of the transfer would be addressed by the provisions of the proposed Winddown Rule and Corporation Default Rule, as defined and described below, and that the Transferee would not acquire any pending or open transactions with the transfer of the business. The Wind-down Plan would anticipate that the Transferee would accept transactions for processing with a trade date from and after the effective time of the transfer.

The Wind-down Plan would provide that, following the effectiveness of the transfer to the Transferee, the wind-down of NSCC would involve addressing any residual claims against NSCC through the bankruptcy process and liquidating the legal entity. As such, and as stated above, the Wind-down Plan does not contemplate NSCC continuing to provide services in any capacity following the transfer time, and any services not transferred would be terminated.

The Wind-down Plan would also identify the key dependencies for the effectiveness of the transfer, which include regulatory approvals that would

permit the Transferee to be legally qualified to provide the transferred services from and after the transfer, and approval by the applicable bankruptcy court of, among other things, the proposed sale, assignments, and transfers to the Transferee.

The Wind-down Plan would address governance matters related to the execution of the transfer of NSCC's business and its wind-down. The Winddown Plan would address the duties of the Board to execute the wind-down of NSCC in conformity with (1) the Rules, (2) the Board's fiduciary duties, which mandate that it exercise reasonable business judgment in performing these duties, and (3) NSCC's regulatory obligations under the Act as a registered clearing agency. The Wind-down Plan would also identify certain factors the Board may consider in making these decisions, which would include, for example, whether NSCC could safely stabilize the business and protect its value without seeking bankruptcy protection, and NSCC's ability to continue to meet its regulatory requirements.

The Wind-down Plan would describe (1) actions NSCC or DTCC may take to prepare for wind-down in the period before NSCC experiences any financial distress, (2) actions NSCC would take both during the recovery phase and the Runway Period to prepare for the execution of the Wind-down Plan, and (3) actions NSCC would take upon commencement of bankruptcy proceedings to effectuate the Wind-down Plan.

Finally, the Wind-down Plan would include an analysis of the estimated time and costs to effectuate the plan, and would provide that this estimate be reviewed and approved by the Board annually. In order to estimate the length of time it might take to achieve a recovery or orderly wind-down of NSCC's critical operations, as contemplated by the R&W Plan, the Wind-down Plan would include an analysis of the possible sequencing and length of time it might take to complete an orderly wind-down and transfer of critical operations, as described in earlier sections of the R&W Plan. The Wind-down Plan would also include in this analysis consideration of other factors, including the time it might take to complete any further attempts at recovery under the Recovery Plan. The Wind-down Plan would then multiply this estimated length of time by NSCC's average monthly operating expenses, including adjustments to account for changes to NSCC's profit and expense profile during these circumstances, over the previous twelve months to

determine the amount of LNA that it should hold to achieve a recovery or orderly wind-down of NSCC's critical operations. The estimated wind-down costs would constitute the "Recovery/Wind-down Capital Requirement" under the Capital Policy. ⁵² Under that policy, the General Business Risk Capital Requirement is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement. ⁵³

The R&W Plan is designed as a roadmap, and the types of actions that may be taken both leading up to and in connection with implementation of the Wind-down Plan would be primarily addressed in other supporting documentation referred to therein.

The Wind-down Plan would address proposed Rule 41 (Corporation Default) and proposed Rule 42 (Wind-down of the Corporation), which would be adopted to facilitate the implementation of the Wind-down Plan, and are discussed below.

Proposed Rules

In connection with the adoption of the R&W Plan, NSCC is proposing to adopt the Proposed Rules, each described below. The Proposed Rules would facilitate the execution of the R&W Plan and would provide Members and Limited Members with transparency as to critical aspects of the Plan, particularly as they relate to the rights and responsibilities of both NSCC and Members. The Proposed Rules also provide a legal basis to these aspects of the Plan.

Rule 41 (Corporation Default)

The proposed Rule 41 ("Corporation Default Rule") would provide a mechanism for the termination, valuation and netting of unsettled, guaranteed CNS transactions in the event NSCC is unable to perform its obligations or otherwise suffers a defined event of default, such as entering insolvency proceedings. The proposed Corporation Default Rule would provide Members with transparency and certainty regarding what would happen if NSCC were to fail (defined in the proposed Rule as a "Corporation Default").

The proposed rule would define the events that would constitute a Corporation Default, which would generally include (1) the failure of NSCC to make any undisputed payment or delivery to a Member if such failure is not remedied within seven days after notice of such failure is given to NSCC;

⁵¹ The proposed transfer arrangements outlined in the Wind-down Plan do not contemplate the transfer of any credit or funding agreements, which are generally not assignable by NSCC. However, to the extent the Transferee adopts rules substantially identical to those NSCC has in effect prior to the transfer, it would have the benefit of any rulesbased liquidity funding. The Wind-down Plan contemplates that no Clearing Fund would be transferred to the Transferee, as it is not held in a bankruptcy remote manner and it is the primary prefunded liquidity resource to be accessed in the recovery phase.

⁵² See supra note 10.

⁵³ See supra note 10.

(2) NSCC is dissolved; (3) NSCC institutes a proceeding seeking a judgment of insolvency or bankruptcy, or a proceeding is instituted against it seeking a judgment of bankruptcy or insolvency and such judgment is entered; or (4) NSCC seeks or becomes subject to the appointment of a receiver, trustee or similar official pursuant to the federal securities laws or Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act ⁵⁴ for it or for all or substantially all of its assets.

Upon a Corporation Default, the proposed Corporation Default Rule would provide that all unsettled, guaranteed CNS transactions would be terminated and, no later than forty-five days from the date on which the event that constitutes a Corporation Default occurred (or "Default Date"), the Board would determine a single net amount owed by or to each Member with respect to such transactions pursuant to the valuation procedures set forth in the Proposed Rule. Essentially, for each affected position in a CNS Security, the "CNS Market Value" would be determined by using the Current Market Price for that security as determined in the CNS System as of the close of business on the next Business Day following the Default Date. NSCC would determine a "Net Contract Value" for each Member's net unsettled long or short position in a CNS Security by netting the Member's (i) contract price for such net position that, as of the Default Date, has not yet passed the Settlement Date, and (ii) the Current Market Price in the CNS System on the Default Date for its fail positions. To determine each Member's "CNS Closeout Value," (i) the Net Contract Value for each CUSIP would be subtracted from the CNS Market Value for such CUSIP, and (ii) the resulting difference for all CUSIPS in which the Member had a net long or short position would be summed, and would be netted and offset against any other amounts that may be due to or owing from the Member under the Rules. The proposed Corporation Default Rule would provide for notification to each Member of its CNS Close-out Value, and would also address interpretation of the Rules in relation to certain terms that are defined in the Federal Deposit Insurance Corporation Improvement Act of 1991 ("FDICIA").55

NSCC believes this valuation approach, which is comparable to the approach adopted by other central counterparties, is appropriate for NSCC given the market in which NSCC operates and the volumes of transactions it processes in CNS, because it would provide for a common, clear and transparent valuation methodology and price per CUSIP applicable to all affected Members.

Rule 42 (Wind-Down of the Corporation)

The proposed Rule 42 ("Wind-down Rule") would be adopted to facilitate the execution of the Wind-down Plan. The Wind-down Rule would include a proposed set of defined terms that would be applicable only to the provisions of this Proposed Rule. The Wind-down Rule would make clear that a wind-down of NSCC's business would occur (1) after a decision is made by the Board, and (2) in connection with the transfer of NSCC's services to a Transferee, as described therein. Generally, the proposed Wind-down Rule is designed to create clear mechanisms for the transfer of Eligible Members, Eligible Limited Members, and Settling Banks (as these terms would be defined in the Wind-down Rule), and NSCC's business, in order to provide for continued access to critical services and to minimize disruption to the markets in the event the Wind-down Plan is initiated.

Wind-down Trigger. First, the Proposed Rule would make clear that the Board is responsible for initiating the Wind-down Plan, and would identify the criteria the Board would consider when making this determination. As provided for in the Wind-down Plan and in the proposed Wind-down Rule, the Board would initiate the Plan if, in the exercise of its business judgment and subject to its fiduciary duties, it has determined that the execution of the Recovery Plan has not or is not likely to restore NSCC to viability as a going concern, and the implementation of the Wind-down Plan, including the transfer of NSCC's business, is in the best interests of NSCC, Members and Limited Members, its shareholders and creditors, and the U.S. financial markets.

Identification of Critical Services;
Designation of Dates and Times for
Specific Actions. The Proposed Rule
would provide that, upon making a
determination to initiate the Winddown Plan, the Board would identify
the critical and non-critical services that
would be transferred to the Transferee at
the Transfer Time (as defined below and
in the Proposed Rule), as well as any
non-critical services that would not be
transferred to the Transferee. The
proposed Wind-down Rule would
establish that any services transferred to
the Transferee will only be provided by

the Transferee as of the Transfer Time, and that any non-critical services that are not transferred to the Transferee would be terminated at the Transfer Time. The Proposed Rule would also provide that the Board would establish (1) an effective time for the transfer of NSCC's business to a Transferee ("Transfer Time"), (2) the last day that transactions may be submitted to NSCC for processing ("Last Transaction Acceptance Date"), and (3) the last day that transactions submitted to NSCC will be settled ("Last Settlement Date").

Treatment of Pending Transactions. The Wind-down Rule would also authorize the Board to provide for the settlement of pending transactions prior to the Transfer Time, so long as the Corporation Default Rule has not been triggered. For example, the Proposed Rule would provide the Board with the ability to, if it deems practicable, based on NŠCC's resources at that time, allow pending transactions to complete prior to the transfer of NSCC's business to a Transferee. The Board would also have the ability to allow Members to only submit trades that would effectively offset pending positions or provide that transactions will be processed in accordance with special or exception processing procedures. The Proposed Rule is designed to enable these actions in order to facilitate settlement of pending transactions and reduce claims against NSCC that would have to be satisfied after the transfer has been effected. If none of these actions are deemed practicable (or if the Corporation Default Rule has been triggered), then the provisions of the proposed Corporation Default Rule would apply to the treatment of open, pending transactions.

The Proposed Rule would make clear, however, that NSCC would not accept any transactions for processing after the Last Transaction Acceptance Date or which are designated to settle after the Last Settlement Date. Any transactions to be processed and/or settled after the Transfer Time would be required to be submitted to the Transferee, and would not be NSCC's responsibility.

Notice Provisions. The proposed Wind-down Rule would provide that, upon a decision to implement the Winddown Plan, NSCC would provide Members and Limited Members and its regulators with a notice that includes material information relating to the Wind-down Plan and the anticipated transfer of NSCC's membership and business, including, for example, (1) a brief statement of the reasons for the decision to implement the Wind-down Plan; (2) identification of the Transferee and information regarding the

⁵⁴ 12 U.S.C. 5381–5394.

⁵⁵ 12 U.S.C. 1811 *et seq*.

transaction by which the transfer of NSCC's business would be effected; (3) the Transfer Time, Last Transaction Acceptance Date, and Last Settlement Date; and (4) identification of Eligible Members and Eligible Limited Members, and the critical and non-critical services that would be transferred to the Transferee at the Transfer Time, as well as those Non-Eligible Members and Non-Eligible Limited Members (as defined in the Proposed Rule), and any non-critical services that would not be included in the transfer. NSCC would also make available the rules and procedures and membership agreements of the Transferee.

Transfer of Membership. The proposed Wind-down Rule would address the expected transfer of NSCC's membership to the Transferee, which NSCC would seek to effectuate by entering into an arrangement with a Failover Transferee, or by using commercially reasonable efforts to enter into such an arrangement with a Third Party Transferee. Therefore, the Winddown Rule would provide Members, Limited Members and Settling Banks with notice that, in connection with the implementation of the Wind-down Plan and with no further action required by any party, (1) their membership with NSCC would transfer to the Transferee, (2) they would become party to a membership agreement with such Transferee, and (3) they would have all of the rights and be subject to all of the obligations applicable to their membership status under the rules of the Transferee. These provisions would not apply to any Member or Limited Member that is either in default of an obligation to NSCC or has provided notice of its election to withdraw from membership. Further, the proposed Wind-down Rule would make clear that it would not prohibit (1) Members and Limited Members that are not transferred by operation of the Winddown Rule from applying for membership with the Transferee, or (2) Members, Limited Members, and Settling Banks that would be transferred to the Transferee from withdrawing from membership with the Transferee.⁵⁶

Comparability Period. The proposed automatic mechanism for the transfer of NSCC's membership is intended to provide NSCC's membership with continuous access to critical services in the event of NSCC's wind-down, and to

facilitate the continued prompt and accurate clearance and settlement of securities transactions. Further to this goal, the proposed Wind-down Rule would provide that NSCC would enter into arrangements with a Failover Transferee, or would use commercially reasonable efforts to enter into arrangements with a Third Party Transferee, providing that, in either case, with respect to the critical services and any non-critical services that are transferred from NSCC to the Transferee, for at least a period of time to be agreed upon ("Comparability Period"), the business transferred from NSCC to the Transferee would be operated in a manner that is comparable to the manner in which the business was previously operated by NSCC. Specifically, the proposed Wind-down Rule would provide that: (1) The rules of the Transferee and terms of membership agreements would be comparable in substance and effect to the analogous Rules and membership agreements of NSCC; (2) the rights and obligations of any Members, Limited Members and Settling Banks that are transferred to the Transferee would be comparable in substance and effect to their rights and obligations as to NSCC; and (3) the Transferee would operate the transferred business and provide any services that are transferred in a comparable manner to which such services were provided by NSCC. The purpose of these provisions and the intended effect of the proposed Winddown Rule is to facilitate a smooth transition of NSCC's business to a Transferee and to provide that, for at least the Comparability Period, the Transferee (1) would operate the transferred business in a manner that is comparable in substance and effect to the manner in which the business was operated by NSCC, and (2) would not require sudden and disruptive changes in the systems, operations and business practices of the new members of the Transferee.

Subordination of Claims Provisions and Miscellaneous Matters. The proposed Wind-down Rule would also include a provision addressing the subordination of unsecured claims against NSCC of Members and Limited Members who fail to participate in NSCC's recovery efforts (i.e., such firms are delinquent in their obligations to NSCC or elect to retire from NSCC in order to minimize their obligations with respect to the allocation of losses, pursuant to the Rules). This provision is

designed to incentivize Members to participate in NSCC's recovery efforts.⁵⁷

The proposed Wind-down Kule would address other ex-ante matters including provisions providing that Members, Limited Members and Settling Banks (1) will assist and cooperate with NSCC to effectuate the transfer of NSCC's business to a Transferee, (2) consent to the provisions of the rule, and (3) grant NSCC power of attorney to execute and deliver on their behalf documents and instruments that may be requested by the Transferee. Finally, the Proposed Rule would include a limitation of liability for any actions taken or omitted to be taken by NSCC pursuant to the Proposed Rule. The purpose of the limitation of liability is to facilitate and protect NSCC's ability to act expeditiously in response to extraordinary events. As noted, such limitation of liability would be available only following triggering of the Winddown Plan. In addition, and as a separate matter, the limitation of liability provides Members with transparency for the unlikely situation when those extraordinary events could occur, as well supporting the legal framework within which NSCC would take such actions. These provisions, collectively, are designed to enable NSCC to take such acts as the Board determines necessary to effectuate an orderly transfer and wind-down of its business should recovery efforts prove unsuccessful.

Rule 60 (Market Disruption and Force Majeure)

The proposed Rule 60 ("Force Majeure Rule") would address NSCC's authority to take certain actions upon the occurrence, and during the pendency, of a "Market Disruption Event," as defined therein. The Proposed Rule is designed to clarify NSCC's ability to take actions to address extraordinary events outside of the control of NSCC and of its membership, and to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Force Majeure Rule, NSCC would be entitled, during the pendency of a Market Disruption Event, to (1) suspend the provision of any or

⁵⁶ The Members and Limited Members whose membership is transferred to the Transferee pursuant to the proposed Wind-down Rule would submit transactions to be processed and settled subject to the rules and procedures of the Transferee, including any applicable margin charges or other financial obligations.

⁵⁷ Nothing in the proposed Wind-down Rule would seek to prevent a Member, Limited Member or Settling Bank that retired its membership at NSCC from applying for membership with the Transferee. Once its NSCC membership is terminated, however, such firm would not be able to benefit from the membership assignment that would be effected by this proposed Wind-down Rule, and it would have to apply for membership directly with the Transferee, subject to its membership application and review process.

all services, and (2) take, or refrain from taking, or require Members and Limited Members to take, or refrain from taking, any actions it considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of NSCC's services as may be practicable.

The proposed Force Majeure Rule would identify the events or circumstances that would be considered a "Market Disruption Event," including, for example, events that lead to the suspension or limitation of trading or banking in the markets in which NSCC operates, or the unavailability or failure of any material payment, bank transfer, wire or securities settlement systems. The proposed Force Majeure Rule would define the governance procedures for how NSCC would determine whether, and how, to implement the provisions of the rule. A determination that a Market Disruption Event has occurred would generally be made by the Board, but the Proposed Rule would provide for limited, interim delegation of authority to a specified officer or management committee if the Board would not be able to take timely action. In the event such delegated authority is exercised, the proposed Force Majeure Rule would require that the Board be convened as promptly as practicable, no later than five Business Days after such determination has been made, to ratify, modify, or rescind the action. The proposed Force Majeure Rule would also provide for prompt notification to the Commission, and advance consultation with Commission staff, when practicable, including notification when an event is no longer continuing and the relevant actions are terminated. The Proposed Rule would require Members and Limited Members to notify NSCC immediately upon becoming aware of a Market Disruption Event, and, likewise, would require NSCC to notify Members and Limited Members if it has triggered the Proposed Rule and of actions taken or intended to be taken thereunder.

Finally, the Proposed Rule would address other related matters, including a limitation of liability for any failure or delay in performance, in whole or in part, arising out of the Market Disruption Event. The purpose of the limitation of liability would be similar to the purpose of the analogous provision in the proposed Wind-down Rule, which is to facilitate and protect NSCC's ability to act expeditiously in response to extraordinary events.

Proposed Change to the Rule Numbers

In order to align the order of the Proposed Rules with the order of comparable rules in the rulebooks of the other Clearing Agencies, NSCC is also proposing to re-number the current Rule 42 (Wind-down of a Member, Fund Member or Insurance Carrier/Retirement Services Member) to Rule 40, which is currently reserved for future use, as shown on Exhibit 5b, hereto.

(a) Statutory Basis

NSCC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, NSCC believes that the R&W Plan, each of the Proposed Rules, and the proposed change to Rule numbers are consistent with Section 17A(b)(3)(F) of the Act,⁵⁸ the R&W Plan and each of the Proposed Rules are consistent with Rule 17Ad–22(e)(3)(ii) under the Act,⁵⁹ and the R&W Plan is consistent with Rule 17Ad–22(e)(15)(ii) under the Act,⁶⁰ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of NSCC be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible. 61 The Recovery Plan and the proposed Force Majeure Rule would promote the prompt and accurate clearance and settlement of securities transactions by providing NSCC with a roadmap for actions it may employ to mitigate losses, and monitor and, as needed, stabilize, its financial condition, which would allow it to continue its critical clearance and settlement services in stress situations. Further, as described above, the Recovery Plan is designed to identify the actions and tools NSCC may use to address and minimize losses to both NSCC and Members. The Recovery Plan and the proposed Force Majeure Rule would provide NSCC's management and the Board with guidance in this regard by identifying the indicators and governance around the use and application of such tools to enable them to address stress situations in a manner most appropriate for the circumstances. Therefore, the Recovery Plan and the proposed Force Majeure Rule would also contribute to the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible by enabling actions that would address and minimize losses.

The Wind-down Plan and the proposed Corporation Default Rule and Wind-down Rule, which would both facilitate the implementation of the Wind-down Plan, would also promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible. The Wind-down Plan and the proposed Corporation Default Rule and Wind-down Rule would collectively establish a framework for the transfer and orderly wind-down of NSCC's business. These proposals would establish clear mechanisms for the transfer of NSCC's critical services and membership, and for the treatment of open, guaranteed CNS transactions in the event of NSCC's default. By doing so, the Wind-down Plan and these Proposed Rules are designed to facilitate the continuity of NSCC's critical services and enable Members and Limited Members to maintain access to NSCC's services through the transfer of its membership in the event NSCC defaults or the Wind-down Plan is triggered by the Board. Therefore, by facilitating the continuity of NSCC's critical clearance and settlement services, NSCC believes the proposals would promote the prompt and accurate clearance and settlement of securities transactions. Further, by creating a framework for the transfer and orderly wind-down of NSCC's business, NSCC believes the proposals would enhance the safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible.

Finally, the proposed change to the Rule numbers would align the order of the Proposed Rules with the order of comparable rules in the rulebooks of the other Clearing Agencies. Therefore, NSCC believes the proposed change would create ease of reference, particularly for Members that are also participants of the other Clearing Agencies, and, as such, would assist in promoting the prompt and accurate clearance and settlement of securities transactions.

Therefore, NSCC believes the R&W Plan, each of the Proposed Rules, and the proposed change to Rule numbers are consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁶²

Rule 17Ad–22(e)(3)(ii) under the Act requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity,

⁵⁸ 15 U.S.C. 78q-1(b)(3)(F).

⁵⁹ 17 CFR 240.17Ad-22(e)(3)(ii).

⁶⁰ *Id.* at 240.17Ad–22(e)(15)(ii).

^{61 15} U.S.C. 78q-1(b)(3)(F).

⁶² Id.

operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses. ⁶³ The R&W Plan and the Proposed Rules are designed to meet the requirements of Rule 17Ad–22(e)(3)(ii). ⁶⁴

The R&W Plan would be maintained by NSCC in compliance with Rule 17Ad-22(e)(3)(ii) in that it provides plans for the recovery and orderly winddown of NSCC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described above. 65 Specifically, the Recovery Plan would define the risk management activities, stress conditions and indicators, and tools that NSCC may use to address stress scenarios that could eventually prevent it from being able to provide its critical services as a going concern. Through the framework of the Crisis Continuum, the Recovery Plan would address measures that NSCC may take to address risks of credit losses and liquidity shortfalls, and other losses that could arise from a Member default. The Recovery Plan would also address the management of general business risks and other non-default risks that could lead to losses.

The Wind-down Plan would be triggered by a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning NSCC to viability as a going concern. Once triggered, the Winddown Plan would set forth clear mechanisms for the transfer of NSCC's membership and business, and would be designed to facilitate continued access to NSCC's critical services and to minimize market impact of the transfer. By establishing the framework and strategy for the execution of the transfer and wind-down of NSCC in order to facilitate continuous access to NSCC's critical services, the Wind-down Plan establishes a plan for the orderly winddown of NSCC. Therefore, NSCC believes the R&W Plan would provide plans for the recovery and orderly winddown of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, and, as such, meets the requirements of Rule 17Ad-22(e)(3)(ii).66

As described in greater detail above, the Proposed Rules are designed to facilitate the execution of the R&W Plan, provide Members and Limited Members with transparency regarding the material provisions of the Plan, and provide NSCC with a legal basis for implementation of those provisions. As such, NSCC also believes the Proposed Rules meet the requirements of Rule 17Ad–22(e)(3)(ii).⁶⁷

NSCC has evaluated the recovery tools that would be identified in the Recovery Plan and has determined that these tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to NSCC's Members to manage the risks they present. The recovery tools, as outlined in the Recovery Plan and in the proposed Force Majeure Rule, provide NSCC with a comprehensive set of options to address its material risks and support the resiliency of its critical services under a range of stress scenarios. NSCC also believes the recovery tools are effective, as NSCC has both legal basis and operational capability to execute these tools in a timely and reliable manner. Many of the recovery tools are provided for in the Rules; Members are bound by the Rules through their membership agreements with NSCC, and the Rules are adopted pursuant to a framework established by Rule 19b–4 under the Act,68 providing a legal basis for the recovery tools found therein. Other recovery tools have legal basis in contractual arrangements to which NSCC is a party, as described above. Further, as many of the tools are embedded in NSCC's ongoing risk management practices or are embedded into its predefined default-management procedures, NSCC is able to execute these tools, in most cases, when needed and without material operational or organizational delay.

The majority of the recovery tools are also transparent, as they are, or are proposed to be, included in the Rules, which are publicly available. NSCC believes the recovery tools also provide appropriate incentives to the Members, as they are designed to control the amount of risk they present to NSCC's clearance and settlement system. Members' financial obligations to NSCC, particularly their Required Deposits to the Clearing Fund, are measured by the risk posed by the Members' activity in NSCC's systems, which incentivizes them to manage that risk which would correspond to lower financial obligations. Finally, NSCC's Recovery Plan provides for a continuous

evaluation of the systemic consequences of executing its recovery tools, with the goal of minimizing their negative impact. The Recovery Plan would outline various indicators over a timeline of increasing stress, the Crisis Continuum, with escalation triggers to NSCC management or the Board, as appropriate. This approach would allow for timely evaluation of the situation and the possible impacts of the use of a recovery tool in order to minimize the negative effects of the stress scenario. Therefore, NSCC believes that the recovery tools that would be identified and described in its Recovery Plan, including the authority provided to it in the proposed Force Majeure Rule, would meet the criteria identified within guidance published by the Commission in connection with the adoption of Rule 17Ad-22(e)(3)(ii).69

Therefore, NSCC believes the R&W Plan and each of the Proposed Rules are consistent with Rule 17Ad—22(e)(3)(ii).⁷⁰

Rule 17Ad-22(e)(15)(ii) under the Act requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage its general business risk and hold sufficient LNA to cover potential general business losses so that NSCC can continue operations and services as a going concern if those losses materialize, including by holding LNA equal to the greater of either (x) six months of the covered clearing agency's current operating expenses, or (y) the amount determined by the board of directors to be sufficient to ensure a recovery or orderly wind-down of critical operations and services of the covered clearing agency.⁷¹ While the Capital Policy addresses how NSCC holds LNA in compliance with these requirements, the Wind-down Plan would include an analysis that would estimate the amount of time and the costs to achieve a recovery or orderly wind-down of NSCC's critical operations and services, and would provide that the Board review and approve this analysis and estimation annually. The Wind-down Plan would also provide that the estimate would be the "Recovery/Winddown Capital Requirement" under the Capital Policy. Under that policy, the General Business Risk Capital Requirement, which is the sufficient amount of LNA that NSCC should hold to cover potential general business losses so that it can continue operations and services as a going concern if those

^{63 17} CFR 240.17Ad-22(e)(3)(ii).

⁶⁴ Id.

⁶⁵ Id.

⁶⁶ Id.

⁶⁷ Id.

⁶⁸ Id. at 240.19b-4.

⁶⁹ Supra note 46.

^{70 17} CFR 240.17Ad-22(e)(3)(ii).

⁷¹ Id. at 240.17Ad-22(e)(15)(ii).

losses materialize, is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement. Therefore, NSCC believes the R&W Plan, as it interrelates with the Capital Policy, is consistent with Rule 17Ad–22(e)(15)(ii).⁷²

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe the proposal would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act.⁷³ The proposal would apply uniformly to all Members and Limited Members. NSCC does not anticipate that the proposal would affect its day-to-day operations under normal circumstances, or in the management of a typical Member default scenario or non-default event. NSCC is not proposing to alter the standards or requirements for becoming or remaining a Member, or otherwise using its services. NSCC also does not propose to change its methodology for calculation of margin or Clearing Fund contributions. The proposal is intended to (1) address the risk of loss events and identify the tools and resources available to it to withstand and recover from such events, so that it can restore normal operations, and (2) provide a framework for its orderly wind-down and the transfer of its business in the event those recovery tools do not restore NSCC to financial viability, as described herein.

The R&W Plan and each of the Proposed Rules have been developed and documented in order to satisfy applicable regulatory requirements, as discussed above.

With respect to the Recovery Plan, the proposal generally reflects NSCC's existing tools and existing internal procedures. Existing tools that would have a direct impact on the rights, responsibilities or obligations of Members are reflected in the existing Rules or are proposed to be included in the Rules. Accordingly, the Recovery Plan and the proposed Force Majeure Rule are intended to provide a roadmap, define the strategy and identify the tools available to NSCC in connection with its recovery efforts. By proposing to enhance NSCC's existing internal management and its regulatory compliance related to its recovery efforts, NSCC does not believe the Recovery Plan or the proposed Force Majeure Rule would have any impact, or impose any burden, on competition.

With respect to the Wind-down Plan, the proposed Corporation Default Rule, and the proposed Wind-down Rule, which facilitate the execution of the Wind-down Plan, the proposal would operate to effect the transfer of all eligible Members and Limited Members to the Transferee, and would not prohibit any market participant from either bidding to become the Transferee or from applying for membership with the Transferee. The proposal also would not prohibit any Member or Limited Member from withdrawing from NSCC prior to the Transfer Time, as is permitted under the Rules today, or from applying for membership with the Transferee. Therefore, as the proposal would treat each similarly situated Member identically under the Winddown Plan and under these Proposed Rules, NSCC does not believe the Winddown Plan, the proposed Corporation Default Rule, or the proposed Winddown Rule would have any impact, or impose any burden, on competition.

NSCC does not believe that the proposed change to the Rule numbers would have any impact on competition because this proposed change is technical in nature and would not change NSCC's current practices or the rights or obligations of Members

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

While NSCC has not solicited or received any written comments relating to this proposal, NSCC has conducted outreach to Members in order to provide them with notice of the proposal. NSCC will notify the Commission of any written comments received by NSCC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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–NSCC–2017–017 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–NSCC–2017–017. 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 website (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 website 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 NSCC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NSCC-2017-017 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 74

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15367 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

 $\quad \hbox{Extension:} \\$

Regulation SCI, Form SCI; SEC File No. 270–653, OMB Control No. 3235–0703.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission

⁷² *Id.* ⁷³ 15 U.S.C. 78q–1(b)(3)(I).

^{74 17} CFR 200.30-3(a)(12).

("Commission") is soliciting comments on the collection of information provided for in Regulation Systems Compliance and Integrity ("Regulation SCI") (17 CFR 242.1000–1007) and Form SCI (17 CFR 249.1900) under the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. 78a et seq.). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Regulation SCI requires certain key market participants to, among other things: (1) Have comprehensive policies and procedures in place to help ensure the robustness and resiliency of their technological systems, and also that their technological systems operate in compliance with the federal securities laws and with their own rules; and (2) provide certain notices and reports to the Commission to improve Commission oversight of securities market infrastructure.

Regulation SCI advances the goals of the national market system by enhancing the capacity, integrity, resiliency, availability, and security of the automated systems of entities important to the functioning of the U.S. securities markets, as well as reinforcing the requirement that such systems operate in compliance with the Exchange Act and rules and regulations thereunder, thus strengthening the infrastructure of the U.S. securities markets and improving its resilience when technological issues arise. In this respect, Regulation SCI establishes an updated and formalized regulatory framework, thereby helping to ensure more effective Commission oversight of such systems.

Respondents consist of national securities exchanges and associations, registered clearing agencies, exempt clearing agencies, plan processors, and alternative trading systems. There are currently 42 respondents, and the Commission staff estimates that, on average, 2 new respondents may become SCI entities each year, 1 of which would be a self-regulatory organization. Accordingly, Commission staff estimates that over the next three years there will be an average of 44 respondents per year.

Rule 1001(a) requires each SCI entity to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems and, for purposes of security standards, indirect SCI systems, have levels of capacity, integrity, resiliency, availability, and security, adequate to maintain the SCI entity's operational capability and promote the maintenance of fair and orderly markets.

The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 1,388 hours (694 hours per respondent × 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 10,208 hours (232 hours per respondent \times 44 respondents). The Commission staff estimates that the 2 new respondents would incur, on average, an annual initial internal cost of compliance of \$465,656 (\$232,828 per respondent × 2 respondents), as well as outside legal or consulting costs of \$94,000 (\$47,000 per respondent × 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$3,426,632 (\$77,878 per respondent × 44 respondents).

Rule 1001(b) requires each SCI entity to establish, maintain, and enforce written policies and procedures reasonably designed to ensure that its SCI systems operate in a manner that complies with the Exchange Act and the rules and regulations thereunder and the entity's rules and governing documents, as applicable. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 540 hours (270 hours per respondent \times 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 6,820 hours (175 hours per SRO respondent × 33 respondents + 95 hours per non-SRO respondent × 11 non-SRO respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of 203,160 (\$101,580 per respondent × 2 respondents), as well as outside legal or consulting costs of \$54,000 (\$27,000 per respondent \times 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of 2,155,780 (\$86,230 per respondent × 44 respondents).

Rule 1001(c) requires each SCI entity to establish, maintain, and enforce reasonably designed written policies and procedures that include the criteria for identifying responsible SCI personnel, the designation and documentation of responsible SCI personnel, and escalation procedures to quickly inform responsible SCI personnel of potential SCI events. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 228 hours (114 hours per respondent \times 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 1,716

hours (39 hours per respondent × 44 respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of \$85,056 (\$42,528 per respondent × 2 respondents), and all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$684,112 (\$15,548 per respondent × 44 respondents).

Rule 1004 requires each SCI entity to establish standards for the designation of certain members or participants for BC/DR plan testing, to designate members or participants in accordance with these standards, to require participation by designated members or participants in such testing at least annually, and to coordinate such testing on an industry- or sector-wide basis with other SCI entities. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 720 hours (360 hours per respondent \times 2 respondents), and the annual ongoing recordkeeping burden for all respondents that are not plan processors will be, on average, 5,670 hours (135 hours per respondent × 42 respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of \$214,596 (\$107,298 per respondent \times 2 respondents). In addition, all respondents that are not plan processors will incur, on average, an estimated ongoing annual internal cost of compliance of \$1,508,850 (\$35,925 per respondent \times 42 respondents). In addition, the Commission staff estimates that the 2 plan processor respondents will incur an estimated ongoing annual cost of \$108,000 for outside legal services (\$54,000 per plan processor respondent \times 2 respondents).

Rule 1002(b)(1) requires each SCI entity, upon any responsible SCI personnel having a reasonable basis to conclude that an SCI event has occurred, to notify the Commission immediately. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 352 hours (8 hours per respondent × 44 respondents). The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$108,394 (\$2,463.25 per respondent × 44 respondents).

Rule 1002(b)(2) requires each SCI entity, within 24 hours of any responsible SCI personnel having a reasonable basis to conclude that the SCI event has occurred, to submit a written notification to the Commission pertaining to the SCI event on a good faith, best efforts basis. These

notifications are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 5,280 hours (120 hours per respondent × 44 respondents). The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$1,739,540 (\$39,535 per respondent × 44 respondents).

Rule 1002(b)(3) requires each SCI entity to provide updates to the Commission pertaining to an SCI event on a regular basis, or at such frequency as reasonably requested by a representative of the Commission, until the SCI event is resolved and the SCI entity's investigation of the SCI event is closed. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 462 hours (10.5 hours per respondent \times 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$144,309 (\$3,279.75 per respondent × 44 respondents).

Rule 1002(b)(4) requires each SCI entity to submit written interim reports, as necessary, and a written final report regarding an SCI event to the Commission. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 7,700 hours (175 hours per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$2,686,860 (\$61,065 per respondent × 44 respondents)

Rule 1002(b)(5) requires each SCI entity to submit to the Commission quarterly reports containing a summary description of any systems disruption or systems intrusion that has had, or the SCI entity reasonably estimates would have, no or a de minimis impact on the SCI entity's operations or on market participants. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 7,040 hours (160 hours per respondent \times 44 respondents). The Commission staff estimates that respondents will incur, on average, an estimated ongoing annual internal cost of compliance of 2,378,728 (\$54,062 per respondent × 44 respondents).

In addition, the Commission staff estimates that respondents will incur, on average, annual costs of \$255,200 ($$5,800 \times 44$ respondents) for outside legal advice in preparation of certain notifications required by Rule 1002(b).

Rule 1002(c)(1)(i) requires each SCI entity, promptly after any responsible SCI personnel has a reasonable basis to conclude that an SCI event (other than a systems intrusion) has occurred, to disseminate certain information to its members or participants. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 924 hours (21 hours per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$604,230 (\$13,732.50 per respondent × 44 respondents).

Rule 1002(c)(1)(ii) requires each SCI entity, when known, to promptly disseminate additional information about an SCI event (other than a systems intrusion) to its members or participants. Rule 1002(c)(1)(iii) requires each SCI entity to provide to its members or participants regular updates of any information required to be disseminated under Rules 1002(c)(1)(i) and (ii) until the SCI event is resolved. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 5,148 hours (117 hours per respondent \times 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$2,033,856 (\$46,224 per respondent × 44 respondents).

Rule 1002(c)(2) requires each SCI entity to disseminate certain information regarding a systems intrusion to its members or participants, and provides an exception when the SCI entity determines that dissemination of such information would likely compromise the security of its SCI systems or indirect SCI systems, or an investigation of the systems intrusion, and documents the reasons for such determination. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 440 hours (10 hours per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$173,415 (\$3,941.25 per respondent \times 44 respondents).

In addition, the Commission staff estimates that all respondents will incur, on average, annual costs of \$146,080 ($$3,320 \times 44$ respondents) for outside legal advice in preparation of certain notifications required by Rule 1002(c).

Rule 1003(a)(1) requires each SCI entity to submit to the Commission quarterly reports describing completed, ongoing, and planned material changes to its SCI systems and security of indirect SCI systems during the prior, current, and subsequent calendar quarters. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 22,000 hours (500 hours per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$6,570,520 (\$149,330 per respondent × 44 respondents).

Rule 1003(a)(2) requires each SCI entity to promptly submit a supplemental report notifying the Commission of a material error in or material omission from a report previously submitted under Rule 1003(a)(1). These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 660 hours (15 hours per respondent \times 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$209,176 (\$4,754 per respondent × 44

respondents). Rule 1003(b)(1) requires each SCI entity to conduct an SCI review of its compliance with Regulation SCI not less than once each calendar year, with an exception for penetration test reviews, which are required to be conducted not less than once every three years. Rule 1003(b)(1) also provides an exception for assessments of SCI systems directly supporting market regulation or market surveillance, which are required to be conducted at a frequency based on the risk assessment conducted as part of the SCI review, but in no case less than once every three years. Rule 1003(b)(2) requires each SCI entity to submit a report of the SCI review to senior management no more than 30 calendar days after completion of the review. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 30,360 hours (690 hours per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$9,724,660 (\$221,015 per respondent × 44 respondents).

Rule 1003(b)(3) requires each SCI entity to submit the report of the SCI review to the Commission and to its

board of directors or the equivalent of such board, together with any response by senior management, within 60 calendar days after its submission to senior management. These reports are required to be submitted on Form SCI. The Commission staff estimates that the total annual ongoing burden for all respondents will be, on average, 44 hours (1 hour per respondent × 44 respondents). The Commission staff estimates that all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$18,128 (\$412 per respondent × 44 respondents).

In addition, the Commission staff estimates that all respondents will incur, on average, annual costs of \$2,200,000 (\$50,000 × 44 respondents) for outside legal advice in preparation of certain notifications required by Rule 1003(b).

Rule 1006 requires each SCI entity, with a few exceptions, to file any notification, review, description, analysis, or report to the Commission required under Regulation SCI electronically on Form SCI through the EFFS. An SCI entity will submit to the Commission an EAUF to register each individual at the SCI entity who will access the EFFS system on behalf of the SCI entity. The Commission staff estimates that the total annual initial burden for 2 new respondents will be 0.6 hours (0.3 hours per respondent \times 2 respondents), and the annual ongoing burden for all respondents will be, on average, 6.6 hours (0.15 hours per respondent \times 44 respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of \$248 ($$124 per respondent \times 2 respondents$), as well as outside costs to obtain a digital ID of \$100 (\$50 per respondent × 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$2,728 (\$62 per respondent × 44 respondents), as well as outside costs to obtain a digital ID of \$2,200 (\$50 per respondent × 44 respondents).

Rule 1002(a) requires each SCI entity, upon any responsible SCI personnel having a reasonable basis to conclude that an SCI event has occurred, to begin to take appropriate corrective action. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 228 hours (114 hours per respondent × 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 1,716 hours (39 hours per respondent × 44 respondents). The Commission staff

estimates that the 2 new respondents would incur an initial internal cost of compliance of \$85,056 (\$42,528 per respondent \times 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$677,468 (\$15,397 per respondent \times 44 respondents).

Rule 1003(a)(1) requires each SCI entity to establish reasonable written criteria for identifying a change to its SCI systems and the security of indirect SCI systems as material. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 228 hours (114 hours per respondent \times 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 1,188 hours (27 hours per respondent \times 44 respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of \$85,056 (\$42,528 per respondent \times 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$507,584 (\$11,536 per respondent \times 44 respondents).

Regulation SCI also requires SCI entities to identify certain types of events and systems. The Commission staff estimates that the total annual initial recordkeeping burden for 2 new respondents will be 396 hours (198 hours per respondent × 2 respondents), and the annual ongoing recordkeeping burden for all respondents will be, on average, 1,716 hours (39 hours per respondent \times 44 respondents). The Commission staff estimates that the 2 new respondents would incur an initial internal cost of compliance of \$139,412 (\$69,706 per respondent \times 2 respondents). In addition, all respondents will incur, on average, an estimated ongoing annual internal cost of compliance of \$677,468 (\$15,397 per respondent × 44 respondents).

Rules 1005 and 1007 establish recordkeeping requirements for SCI entities other than SROs. The Commission staff estimates that for a new respondent that is not an SRO the average annual initial burden would be 170 hours (170 hours \times 1 respondent), and the annual ongoing burden for all respondents will be, on average, 275 hours (25 hours \times 11 respondents). The Commission staff estimates that a new respondent would incur an estimated internal initial internal cost of compliance of \$11,370, as well as a onetime cost of \$900 to modify existing recordkeeping systems. In addition, all respondents will incur, on average, an

estimated ongoing internal cost of compliance of \$18,975 ($$1,725 \times 11$ respondents).

Written comments are invited on: (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 estimates of the burden 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: July 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15381 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83635; File No. SR-CHX-2018-004]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Filing of Amendment Nos. 2 and 3 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendments Nos. 1, 2, and 3 Thereto, in Connection With a Proposed Transaction Involving CHX Holdings, Inc. and the Intercontinental Exchange, Inc.

July 13, 2018.

I. Introduction

On May 8, 2018, the Chicago Stock Exchange, Inc. ("CHX" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act'') 1 and Rule 19b-4 thereunder,2 a proposed rule change in connection with a transaction ("Transaction") whereby a wholly-owned subsidiary of NYSE Group, Inc. ("NYSE Group") would merge with and into the Exchange's parent, CHX Holdings, Inc. ("CHX Holdings"), with CHX Holdings continuing as the surviving corporation. Pursuant to the Transaction, the Exchange and CHX Holdings would become indirect subsidiaries of Intercontinental Exchange, Inc. ("ICE"). On May 17, 2018, the Exchange filed Amendment No. 1 to the proposal.³ The proposed rule change, as modified by Amendment No. 1, was published for comment in the Federal Register on May 29, 2018.4 On June 11, 2018, the Exchange filed Amendment No. 2 to the proposal.⁵ On June 26, 2018, the Exchange filed Amendment No. 3 to the proposal.⁶ The Commission received no comments on the proposal.

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.7 In particular, the Commission finds that the proposed rule change is consistent with Sections 6(b)(1) and (3) of the Exchange Act,8 which, among other things, require a national securities exchange to be so organized and have

the capacity to be able to carry out the purposes of the Exchange Act, and to enforce compliance by its members and persons associated with its members with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the exchange, and assure the fair representation of its members in the selection of its directors and administration of its affairs, and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer. The Commission also finds that the proposal is consistent with Section 6(b)(5) of the Exchange Act,9 which requires that the rules of the exchange be 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.

II. Discussion

A. Current and Proposed Ownership of the Exchange

Currently, the Exchange is a whollyowned subsidiary of CHX Holdings, and CHX Holdings is beneficially owned by 197 firms or individuals, including Participants 10 or affiliates of Participants.

Pursuant to the terms of a Merger Agreement, dated April 4, 2018, by and among CHX Holdings, ICE, and Kondor Merger Sub, Inc., a wholly-owned subsidiary of NYSE Group ("Merger Sub"), Merger Sub would merge with and into CHX Holdings, and CHX Holdings would be the entity surviving the merger. Current holders of the common and preferred stock of CHX Holdings would receive cash in

exchange for their shares.

Upon closing of the Transaction ("Closing"), NYSE Group would hold all of the outstanding and issued shares of CHX Holdings. NYSE Group is a wholly-owned subsidiary of NYSE Holdings, which is in turn wholly owned by ICE Holdings. ICE Holdings is wholly-owned by ICE (together, with NYSE Group, NYSE Holdings, and ICE, the "ICE Holding Companies").11 CHX Holdings would continue to be the record and beneficial owner of all of the issued and outstanding shares of capital stock of CHX and the sole member of

the Exchange's affiliated routing broker dealer, CHXBD, LLC ("CHXBD"). Closing is subject to satisfaction of customary conditions for a transaction of this nature, including approval of this proposed rule change by the Commission.

Following the Transaction, the Exchange would continue to be registered as a national securities exchange and as a separate selfregulatory organization ("SRO"). As such, the Exchange would continue to have separate rules, membership rosters, and listings that would be distinct from the rules, membership rosters, and listings of the four other registered national securities exchanges and SROs owned by NYSE Group, namely, the New York Stock Exchange LLC ("NYSE"), NYSE American LLC ("NYSE American"), NYSE Arca, Inc. ("NYSE Arca"), and NYSE National, Inc. ("NYSE National" and together with NYSE, NYSE American and NYSE Arca, the "NYSE Exchanges").

B. Proposed Rule Changes

Section 19(b) of the Exchange Act and Rule 19b-4 thereunder require an SRO to file proposed rule changes with the Commission. To effectuate the change in the ownership structure in connection with the proposed Transaction, the Exchange has proposed to amend the CHX Certificate, the CHX Bylaws, the CHX Holdings certificate of incorporation ("CHX Holdings Certificate"), CHX Holdings bylaws ("CHX Holdings Bylaws"), and the Exchange's rules. Although CHX Holdings, NYSE Group, NYSE Holdings, ICE Holdings, and ICE are not SROs, certain provisions of their proposed certificates of incorporation and bylaws, along with other corporate documents, are rules of the Exchange, if they are stated policies, practices, or interpretations, as defined in Rule 19b-4 under the Exchange Act, and must be filed with the Commission pursuant to Section 19(b)(1) of the Exchange Act and Rule 19b-4 thereunder.12 Accordingly, the Exchange has filed, and has proposed to adopt, as rules of the Exchange: (1) The certificate of incorporation of NYSE Group ("NYSE Group Certificate"); (2) the bylaws of NYSE Group ("NYSE Group Bylaws"); (3) the limited liability company agreement of NYSE Holdings LLC ("NYSE Holdings Agreement"); (4) the certificate of incorporation of ICE Holdings ("ICE Holdings Certificate"); (5) the bylaws of ICE Holdings ("ICE Holdings Bylaws"); (6) the certificate of

¹ 15 U.S.C. 78s(b)(1).

²¹⁷ CFR 240.19b-4.

³ In Amendment No. 1, the Exchange proposed to: (1) Add new CHX Article 22, Rule 28, relating to requirements for trading securities issued by ICE or its affiliates; and (2) amend proposed CHX Article 19, Rule 2(b), relating to certain requirements with respect to a wholly-owned subsidiary of NYSE Group that would act as an inbound router to the Exchange. Amendment No. 1 was reflected in the notice of filing of proposed rule change that was published in the Federal Register. See infra note 4.

⁴ See Securities Exchange Act Release No. 83303 (May 22, 2018), 83 FR 24517 ("Notice").

⁵ In Amendment No. 2, the Exchange proposed to amend Article FIFTH, Paragraph (g) of the CHX certificate of incorporation ("CHX Certificate") and Article II, Section 6 of the CHX bylaws ("CHX Bylaws") to provide that a vacancy in the CHX board of directors would be filled either by the remaining director(s) or stockholder action. Amendment No. 2 is available at: https:// www.sec.gov/comments/sr-chx-2018-004/ chx2018004-3818683-162751.pdf.

⁶ In Amendment No. 3, the Exchange proposed technical changes to the CHX Certificate so that the date the original certificate of incorporation was filed and the original name of the Exchange appear in the preamble instead of Article FIRST, and to delete "the" from the title of the CHX Certificate. Amendment No. 3 is available at: https:// www.sec.gov/comments/sr-chx-2018-004/ chx2018004-3918683-166986.pdf.

⁷ In approving the proposed rule changes, the Commission has considered their impact on efficiency, competition and capital formation. See 15 U.S.C. 78c(f).

^{8 15} U.S.C. 78f(b)(1) and (b)(3).

^{9 15} U.S.C. 78f(b)(5).

 $^{^{10}\,\}mathrm{A}$ "Participant" is considered a "member" of the Exchange for purposes of the Exchange Act. See CHX Article 1, Rule 1(s) (Definitions).

¹¹ ICE is a public company listed on the NYSE. ICE, ICE Holdings, and NYSE Group are Delaware corporations and NYSE Holdings is a Delaware limited liability corporation.

¹² See Section 3(a)(27) of the Exchange Act, 15 U.S.C. 78c(a)(27).

incorporation of ICE ("ICE Certificate"); (7) the bylaws of ICE ("ICE Bylaws"); and (8) the independence policy of the board of directors of ICE. In addition, the Exchange has filed with the Commission the text of a proposed resolution of CHX Holdings' board of directors to waive certain ownership and voting limitations to permit the Transaction.

1. Proposed Rule Changes To Waive the Ownership and Voting Limitations

The current CHX Holdings certificate of incorporation ("Current CHX Holdings Certificate") provides that that no Person,13 either alone or together with its Related Persons,14 may, directly or indirectly: (1) Own shares of stock of CHX Holdings representing more than 40 percent of the then outstanding votes entitled to be cast on any matter; (2) if it is a Participant, own shares of stock of CHX Holdings representing more than 20 percent of the then outstanding votes entitled to be cast on any matter; or (3) pursuant to any voting trust, agreement, plan or other arrangement, vote or cause the voting of shares of the stock of CHX Holdings or give any consent or proxy with respect to shares representing more than 20 percent of the voting power of the then issued and outstanding capital stock of CHX Holdings; or enter into any agreement, plan or other arrangement ("Arrangement") with any other Person, either alone or together with its Related Persons, under circumstances that would result in the subject shares of CHX Holdings not being voted on any matter or matters or any proxy relating thereto being withheld, where the effect of such Arrangement would be to enable any Person, either alone or together with its Related Persons, to vote, possess the right to vote or cause the voting of shares of CHX Holdings which would

represent more than 20 percent of such voting power.¹⁵

The CHX Holdings Certificate provides that the first and third ownership and voting limitations set forth above may be waived by the CHX Holdings board of directors by adopting an amendment to the bylaws, if, in connection with the adoption of such amendment, the board of directors also adopts certain resolutions. 16 In addition, the CHX Holdings Certificate provides that, notwithstanding the first and second ownership and voting limitations, a proposed sale, assignment or transfer of CHX Holdings stock above the percentage limitations shall not become effective until the board of directors of CHX Holdings has determined, by resolution, that such purchaser and its Related Persons are not subject to any applicable statutory disqualification.¹⁷

Waiver of the ownership and voting limitations must be filed with and approved by the Commission pursuant to Section 19 of the Exchange Act. 18 Furthermore, such Person seeking the waiver must deliver to the CHX Holdings board of directors not less than 45 days prior to any vote or acquisition, as appropriate, a notice of the intent to exceed the ownership and voting restrictions. 19

Because NYSE Group's acquisition of all of the shares of CHX Holdings at Closing would violate these ownership and voting limitations, the CHX

Holdings board of directors determined that in order to effect the Transaction, a waiver of the ownership and voting limitations with respect to the ICE Holding Companies would be required. To do so, the board of directors adopted resolutions ("Resolutions"), making certain determinations with respect to the ICE Holding Companies and the Transaction that are necessary to waive the ownership and voting limits. Specifically, the board of directors of CHX Holdings made the following determinations: (1) The acquisition of the proposed ownership by the ICE Holdings Companies will not impair the ability of the Exchange to carry out its functions and responsibilities as an "exchange" under the Exchange Act and the rules thereunder; are otherwise in the best interests of CHX Holdings and its stockholders and the Exchange; and will not impair the ability of the Commission to enforce the Exchange Act; and (2) none of the ICE Holding Companies, nor any of its Related Persons, is subject to "statutory disqualification" within the meaning of Section 3(a)(39) of the Exchange Act.

Article IV, Section 2(a) of the proposed CHX Holdings Certificate would ensure that any change in ownership of CHX Holdings would be subject to Commission approval, by providing that NYSE Group may not transfer or assign any stock unless such transfer or assignment is filed with and approved by the Commission under Section 19 of the Exchange Act.²⁰ The governing documents of NYSE Group, NYSE Holdings, and ICE Holdings also provide that any transfer or assignment of stock must be filed with or approved by the Commission under Section 19 of the Exchange Act.²¹ Each of the NYSE Group Certificate, NYSE Holdings Agreement, and ICE Holdings Certificate provides that any changes to the provisions of such agreement must either be filed with and approved by the Commission pursuant to Section 19 of the Exchange Act or must be submitted to the Exchange's board of directors, and if the board so decides, the changes must be filed with and approved by the Commission.22

The Commission believes that it is consistent with the Exchange Act to allow the ICE Holding Companies to wholly-own and vote all of the outstanding common stock of CHX Holdings. The Commission notes that

¹³ Current CHX Holdings Certificate, Article FIFTH, Paragraph (a)(i) defines "Person" as "an individual, partnership (general or limited), joint stock company, corporation, limited liability company, trust or unincorporated organization, or any governmental entity or agency or political subdivision thereof."

¹⁴ Current CHX Holdings Certificate, Article FIFTH, Paragraph (a)(ii) defines "Related Persons" as "(A) with respect to any Person, all 'affiliates' and 'associates' of such Person (as such terms are defined in Rule 12b–2 under the . . . Act . . .); (B) with respect to any Person that holds a permit issued by the . . . Exchange . . . to trade securities on the . . . Exchange (a 'Participant'), any broker or dealer with which a Participant is associated; and (C) any two or more Persons that have any agreement, arrangement or understanding (whether or not in writing) to act together for the purpose of acquiring, voting, holding or disposing of shares of the capital stock of' CHX Holdings.

¹⁵ Article FIFTH, Paragraph (b)(ii) of the Current CHX Holdings Certificate. Article FIFTH includes provisions to address violations of the current ownership and voting limitations. See Article FIFTH, Paragraphs (d) and (e) of the Current CHX Holdings Certificate.

¹⁶ Article FIFTH, Paragraph (b)(iii)(B) of the Current CHX Holdings Certificate, which provides that any such resolution must state that the board of director's determination is that such amendment (a) will not impair the ability of the Exchange to carry out its functions and responsibilities as an "exchange" under the Exchange Act, and the rules under the Exchange Act; (b) is otherwise in the best interests of CHX Holdings and its stockholders and the Exchange; (c) will not impair the ability of the Commission to enforce the Exchange Act, and (d) such amendment shall not be effective until approved by the Commission.

¹⁷ See Article FIFTH, Paragraph (b)(iv) of the Current CHX Holdings Certificate, which provides that, notwithstanding the first and second ownership and voting limitations, "in any case where a Person, either alone or together with its Related Persons, would own or vote more than the above percentage limitations upon consummation of any proposed sale, assignment or transfer of" CHX Holdings' stock, "such sale, assignment or transfer shall not become effective until the Board of Directors' of CHX Holdings "shall have determined, by resolution, that such Person and its Related Persons are not subject to any applicable 'statutory disqualification' (within the meaning of Section 3(a)(39)" of the Exchange Act.

¹⁸ See Article FIFTH, Paragraph (b)(v) of the Current CHX Holdings Certificate.

¹⁹ Id.

²⁰ 15 U.S.C. 78s(b)(1).

²¹ See NYSE Group Certificate Article IV, Section 4(a), NYSE Holdings Agreement Article VII, Section 7.2, and ICE Holdings Certificate Article IV.C.

²² See NYSE Group Certificate Article XII, NYSE Holdings Agreement Article XVI, Section 16.1, and ICE Holdings Certificate Article X.

ICE, the new top-level holding company for the Exchanges, currently owns other national securities exchanges and is subject to governance documents that restrict concentration of ownership and voting rights.²³ As discussed below, CHX Holdings has also included in its corporate documents certain provisions designed to maintain the independence of the Exchange's regulatory functions.²⁴ Accordingly, the Commission does not believe that the Transaction will impair the ability of the Exchange to carry out its functions and responsibilities as an "exchange" under the Exchange Act and the rules and regulations promulgated thereunder, or the ability of the Commission to enforce the Exchange Act and the rules and regulations promulgated thereunder.

2. Ownership and Voting Limitations

In connection with the Transaction, upon Closing, ICE will become the indirect owner (through ICE Holdings, NYSE Holdings, NYSE Group, and CHX Holdings) of the Exchange.²⁵ The ICE Certificate includes restrictions on the ability to own and vote shares of capital stock of ICE. These limitations are designed to prevent any stockholder from exercising undue control over the operation of the Exchange and to assure that the Exchange and the Commission are able to carry out their regulatory obligations under the Exchange Act.

Specifically, the ICE Certificate includes restrictions on the ability to vote and own shares of stock of ICE. For so long as ICE directly or indirectly controls a national securities exchange, the ICE Certificate provides that no person, either alone or together with its related persons, shall be: (1) Entitled to vote or cause the voting of more than 10 percent of the then outstanding votes entitled to be cast on a matter, or (2) permitted to own shares of stock of ICE representing in the aggregate more than 20 percent of the then outstanding votes entitled to be cast on any matter. The ICE Certificate provides that ICE will be required to disregard any votes purported to be cast in excess of the voting restriction. The ICE Certificate

also provides that in the event that any person(s) exceeds the ownership restrictions, it will be obligated to sell promptly, and ICE will be obligated to purchase promptly, at a price equal to the par value of such shares and to the extent funds are legally available for such purchase, the number of shares of ICE necessary so that such person, together with its related persons, will beneficially own shares of ICE representing in the aggregate no more than 20 percent of the then outstanding votes entitled to be cast on any matter, after taking into account that such repurchased shares will become treasury shares and will no longer be deemed to be outstanding. The ICE board of directors may waive the ownership and voting restrictions if it makes certain determinations and expressly resolves to permit the ownership and voting that is subject to such restrictions, and such resolutions have been filed with, and approved by, the Commission under Section 19(b) of the Exchange Act. The ICE Certificate further provides that the board of directors may not approve either voting or ownership rights in excess of a 20 percent threshold with respect to any person that is a member of an exchange controlled by ICE or who is subject to any statutory disqualification.

The Commission believes that ICE's ownership and voting limitations are reasonably designed to prevent any stockholder from exercising undue control over the operation of ICE, and in turn, over the operation of the Exchange. The Commission also notes that these ownership and voting limitations have previously been approved by the Commission ²⁶ and are consistent with those approved by the Commission for other SROs ²⁷ and

believes that they are reasonably designed to assure that the Exchange and the Commission are able to carry out their regulatory obligations under the Exchange Act and in administering and complying with the requirements of the Exchange Act. Moreover, the Commission believes that the ownership and voting limits are reasonably designed to eliminate the potential that the control of the Exchange by one or few stockholders would improperly interfere with or impair the ability of the Commission or the Exchange to effectively carry out their regulatory oversight responsibilities under the Exchange Act.

In addition to being designed to eliminate the potential of any stockholder from exercising undue control over the Exchange, the Commission also notes that the restrictions applicable to members of an exchange are designed to address the conflicts of interests that might result from a member of a national securities exchange owning interests in the exchange. As the Commission has noted in the past, a member's interest in an exchange could become so large as to cast doubts on whether the exchange may fairly and objectively exercise its self-regulatory responsibilities with

(SR-BATS-2013-059, SR-BYX-2013-039) (approving similar restrictions in connection with the merger of BATS Global Markets, Inc. and Direct Edge Holdings LLC); 70210 (August 15, 2013), 78 FR 62716 (August 13, 2010), 75 FR 51295 (August 19, 2010) (File No. 10-198) (approving similar restrictions in connection with the registration Bats BYX Exchange, Inc. as a national securities exchange); 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) (File Nos. 10-194 and 10-196) (approving similar restrictions in connection with the registrations of EDGX Exchange, Inc. and EDGA Exchange, Inc. as national securities exchanges); 58375 (August 18, 2008), 73 FR 49498 (August 21, 2008) (File No. 10-182) (approving similar restrictions in connection with the registration of BATS Exchange, Inc. as a national securities exchange); 56955 (December 13, 2007), 72 FR 71979, 71982-84 (December 19, 2007) (SR-ISE-2007-101) (approving similar restrictions in connection with International Securities Exchange Holdings, Inc. becoming a wholly-owned indirect subsidiary of Eurex Frankfurt AG); 55293 (February 14, 2007); 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR-NYSE-2005-77) (approving similar restrictions in connection with the merger of New York Stock Exchange, Inc. and Archipelago); 53963 (June 8, 2006), 71 FR 34660 (June 15, 2006) (File No. SR-NSX-2006-03) (approving similar restrictions in connection with the demutualization of the National Stock Exchange); 53128 (January 13, 2006), 71 FR 3550 (January 23, 2006) (File No. 10-131) (approving similar restrictions in connection with the registration the Nasdaq Stock Market LLC as a national securities exchange); 51149 (February 8, 2005), 70 FR 7531 (February 14, 2005) (SR-CHX-2004-26) (approving similar restrictions in connection with the demutualization of CHX); and 49098 (January 16, 2004), 69 FR 3974 (January 27, 2004) (SR-Phlx-2003-73) (approving similar restrictions in connection with the demutualization of the Philadelphia Stock Exchange, Inc.).

 $^{^{23}\,}See$ Article V of the ICE Certificate. See infra Section II.B.2.

 $^{^{24}\,}See$ Article XI of the proposed CHX Holdings Certificate and Article III of the proposed CHX Holdings Bylaws.

²⁵ Because the governing documents of CHX Holdings, NYSE Group, NYSE Holdings, and ICE Holdings provide that any transfer or assignment of stock must be filed with or approved by the Commission under Section 19 of the Exchange Act, any change in control of such ICE Holding Companies would be subject to Commission approval. See supra notes 19–22 and accompanying text

²⁶ See, e.g., Securities Exchange Act Release No. 71721 (March 13, 2014), 79 FR 15367 (March 19, 2014) (SR-NYSE-2014-04; SR-NYSEMKT-2014-10; SR-NYSEArca-2014-08).

²⁷ See, e.g., Securities Exchange Act Release Nos. 79585 (December 16, 2016), 81 FR 93988 (December 22, 2016) (SR-BatsBZX-2016-68) (approving similar restrictions in connection with the merger of Bats Global Markets, Inc. and CBOE Holdings, Inc.) ("BATS-CBOE Approval Order"); 78119 (June 21, 2016), 81 FR 41611 (June 27, 2016) (SR-ISE-2016-11, SR-ISE Gemini-2016-05, SR-ISE Mercury–2016–10) (approving similar restrictions proposed in connection with Nasdaq, Inc. becoming the indirect parent of International Securities Exchange, ISE Gemini, LLC, and ISE Mercury, LLC); 74270 (February 13, 2015), 80 FR 9286 (February 20, 2015) (SR-NSX-2014-017) (approving similar restrictions in connection with National Stock Exchange, Inc. becoming a wholly-owned subsidiary of National Stock Exchange Holdings, Inc.); 71449 (January 30, 2014), 79 FR 6961 (February 5, 2014) (SR-EDGA-2013-34; SR-EDGX-2013-43) (approving similar restrictions in connection with the merger of BATS Global Markets, Inc. and Direct Edge Holdings LLC); 71375 (January 23, 2014), 79 FR 4771 (January 29, 2014)

respect to such member.²⁸ A member that is a controlling stockholder of an exchange could seek to exercise that controlling influence by directing the exchange to refrain from, or the exchange may hesitate to, diligently monitor and conduct surveillance of the member's conduct or diligently enforce the exchange's rules and the federal securities laws with respect to conduct by the member that violates such provisions. As such, these restrictions on Exchange members' ownership and voting of ICE stock are expected to minimize the potential that a person or entity can improperly interfere with or restrict the ability of CHX to effectively carry out its regulatory oversight responsibilities under the Exchange Act.

3. Jurisdiction; Books and Records; Due Regard

As described above, following the Closing, ICE will remain the sole stockholder of ICE Holdings, ICE Holdings will remain the sole stockholder of NYSE Holdings, NYSE Holdings will remain the sole member of NYSE Group, NYSE Group will become the sole stockholder of CHX Holdings, and CHX Holdings will remain the sole stockholder of the Exchange. Although ICE, ICE Holdings, NYSE Holdings, NYSE Group, and CHX Holdings will not carry out any regulatory functions, their activities with respect to the operation of the Exchange must be consistent with, and must not interfere with, the selfregulatory obligations of the Exchange. The ICE Bylaws,29 ICE Holdings Bylaws,³⁰ NYSE Holdings Agreement,³¹ NYSE Group Certificate,³² and CHX Holdings Certificate 33 therefore include certain provisions that are designed to maintain the independence of the Exchange's self-regulatory functions, enable the Exchange to operate in a manner that complies with the federal securities laws, including the objectives of Sections 6(b) 34 and 19(g) 35 of the Exchange Act, and facilitate the ability of the Exchange and the Commission to fulfill their regulatory and oversight obligations under the Exchange Act.

For example, under the CHX Holdings Certificate, CHX Holdings, its directors, officers, and employees, must give due regard to the preservation of the independence of the self-regulatory function of the Exchange (to the extent of the Exchange's self-regulatory function), as well as to its obligations to investors and the general public and must not take any actions that would interfere with the effectuation of any decisions by the board of directors of the Exchange relating to its regulatory functions (including disciplinary matters), or which would interfere with the ability of the Exchange to carry out its responsibilities under the Exchange Act. 36

The CHX Holdings Certificate would further require that CHX Holdings complies with the U.S. federal securities laws and rules and regulations thereunder and shall cooperate with the Commission and the Exchange, pursuant to and to the extent of their respective regulatory authority, and shall take reasonable steps necessary to cause its agents to cooperate with the Commission and, where applicable, the Exchange, pursuant to their regulatory authority.³⁷ The CHX Holdings Certificate also provides that CHX Holdings shall take reasonable steps necessary to cause its officers, directors and employees, prior to accepting their positions, to consent to the applicability of Section 7 of Article V ("Considerations of the Board"), Article IX ("Jurisdiction"), Article X ("Confidential Information"), and Section 3 of Article XI of the CHX Holdings Certificate (relating to giving due regard to the independence of the self-regulatory function of the Exchange) with respect to their activities related to the Exchange.³⁸ In addition, the CHX Holdings Certificate provides that in discharging his or her responsibilities as a member of the board or as an officer or employee of CHX Holdings, each such director, officer, or employee shall (1) comply with the federal securities laws and the rules and regulations thereunder, (2) cooperate with the Commission, and (3) cooperate with the Exchange pursuant to and to the extent of its regulatory authority.39 Furthermore, CHX Holdings, its directors and officers, and those of its employees whose principal place of business and residence is outside of the

United States, shall be deemed to irrevocably submit to the jurisdiction of the United States federal courts and the Commission for the purposes of any suit, action, or proceeding pursuant to the United States federal securities laws and the rules and regulations thereunder, commenced or initiated by the Commission arising out of, or relating to, the activities of the Exchange.⁴⁰

The CHX Holdings Certificate also provides that as long as CHX Holdings directly or indirectly controls any national securities exchange, the books, records, premises, officers, directors, and employees of CHX Holdings shall be deemed to be the books, records, premises, officers, directors, and employees of the Exchange for purposes of and subject to oversight pursuant to the Exchange Act.⁴¹

The CHX Holdings Certificate also provides that all confidential information pertaining to the selfregulatory function of the Exchange (including but not limited to disciplinary matters, trading data, trading practices, and audit information) contained in the books and records of the Exchange that shall come into the possession of CHX Holdings, shall not be made available to any persons other than to those officers, directors, employees, and agents of CHX Holdings, that have a reasonable need to know the contents thereof, and shall be retained in confidence by CHX Holdings, and the officers, directors, employees, and agents of CHX Holdings, and not used for any commercial purposes.42 The CHX Holdings Certificate, however, specifies that the CHX Holdings Certificate (including these confidentiality provisions) shall not be interpreted so as to limit or impede the rights of the Commission or the Exchange to access and examine such confidential information pursuant to the federal securities laws and the rules and regulations thereunder, or to limit or impede the ability of any officers, directors, employees, or agents of CHX Holdings to disclose such confidential information to the Commission or the Exchange.43 In addition, the CHX Holdings Certificate provides that CHX Holdings' books and records shall be subject at all times to inspection and

 $^{^{28}}$ See, e.g., BATS–CBOE Order, supra note 27, at 93990.

 $^{^{29}}$ See Articles VII, VIII, IX, and IX of the ICE Bylaws.

 $^{^{30}}$ See Articles VII, VIII, IX, and XI of the ICE Holdings Bylaws.

³¹ See Articles XII, XIII, XIV, and Article XVI, Section 16.1 of the NYSE Holdings Agreement.

³² See Articles IX, X, XI, and XII of the NYSE Group Certificate.

 $^{^{\}rm 33}\,See$ Articles IX, X, XI, and XII of the proposed CHX Holdings Certificate.

^{34 15} U.S.C. 78f(b).

^{35 15} U.S.C. 78s(g).

 $^{^{36}}$ Article XI, Section 3 of the proposed CHX Holdings Certificate.

³⁷ Article XI, Section 1 of the proposed CHX Holdings Certificate.

 $^{^{38}\,\}mathrm{Article}$ XI, Section 2 of the proposed CHX Holdings Certificate.

 $^{^{39}}$ Article V, Section 7 of the proposed CHX Holdings Certificate.

 $^{^{\}rm 40}\,\rm Article~IX$ of the proposed CHX Holdings Certificate.

⁴¹ Article X of the proposed CHX Holdings Certificate.

 $^{^{\}rm 42}$ Article X of the proposed CHX Holdings Certificate.

⁴³ Article X of the proposed CHX Holdings Certificate.

copying by the Commission and the Exchange.⁴⁴

The CHX Holdings Certificate and CHX Holdings Bylaws provide that as long as CHX Holdings controls, directly or indirectly, a registered national securities exchange, before any amendment to, or repeal of, any provision of the CHX Holdings Certificate and CHX Holdings Bylaws, as the case may be, may be effective, those changes must be either filed with or filed with and approved by the Commission under Section 19 of the Exchange Act and the rules promulgated thereunder or submitted to the board of directors of each such exchange, and if the amendment is required to be filed with, or filed with and approved by the Commission pursuant to Section 19(b) of the Exchange Act, such change shall not be effective until filed with, or filed with and approved by, the Commission.45

The Commission finds that these provisions are consistent with the Exchange Act, and that they are intended to assist the Exchange in fulfilling its self-regulatory obligations and in administering and complying with the requirements of the Exchange Act. The Commission also notes that, even in the absence of these provisions, under Section 20(a) of the Exchange Act. 46 any person with a controlling interest in the Exchange shall be jointly and severally liable with and to the same extent that the Exchange is liable under any provision of the Exchange Act, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action. In addition, Section 20(e) of the Exchange Act 47 creates aiding and abetting liability for any person who knowingly provides substantial assistance to another person in violation of any provision of the Exchange Act or rule thereunder. Further, Section 21C of the Exchange Act 48 authorizes the Commission to enter a cease-and-desist order against any person who has been "a cause of" a violation of any provision of the Exchange Act through an act or omission that the person knew or should have known would contribute to the violation.

4. CHX Board of Directors

As noted above, the Exchange will become part of a corporate family including five separate registered national securities exchanges following consummation of the Transaction. The Exchange represented that it is important for each of such exchanges to have a consistent approach to corporate governance in certain matters; therefore, to simplify complexity and create greater consistency among the NYSE Exchanges, CHX proposed to revise the provisions of the CHX Bylaws and CHX Certificate to mirror the comparable provisions in the certain of the NYSE Exchanges.⁴⁹ Specifically, as discussed below, the Exchange proposed to make the number, composition, term of office and qualifications of the Exchange board of directors ("Board") consistent with the make-up of the boards of directors of the NYSE Exchanges.

Currently, the CHX Bylaws generally provide that the Board shall be composed of between 10 and 16 directors, the exact number to be determined by the Board; the CHX Bylaws also set forth the compositional requirements for the Board. The Exchange proposed to amend the CHX Bylaws to provide that the number of directors would be determined from time to time by the stockholders subject to the compositional requirements for the Board, which require that at least 50 percent of the directors on the Exchange's Board be persons from the public and not be, or be affiliated with, a broker-dealer in securities or employed by, or involved in any material business relationship with, the Exchange or its affiliates ("Public Directors"); and at least 20 percent of the directors consist of individuals nominated by the trading permit holders who are permitted to trade on the Exchange's facilities for the trading of equities that are securities as covered by the Exchange Act (collectively, "Permit Holders") (such directors, the "STP Participant Directors").50 The Exchange also proposed that for purposes of calculating the minimum number of STP Participant Directors, if 20 percent of the directors is not a whole number, such number of directors to be nominated and selected by the Permit Holders be rounded up to the next whole number, and that the term of office of a director not be affected by any decrease in the authorized number of directors.⁵¹ The revised provisions also would require the nominees for a

director position to provide to the Secretary of the Exchange such information as is reasonably necessary to serve as the basis for a determination of the nominee's qualifications as a director, and that the Secretary make such determination concerning the nominee's qualifications.⁵²

The Exchange also proposed to amend Article II, Section 2(c) of the CHX Bylaws, which sets forth the structure of the Board. Currently, the Board is divided into three classes serving threeyear terms, with the term of office of one class expiring each year, and directors continue in office after the expiration of their terms until their successors are elected or appointed and qualified, except in the event of early resignation, removal, or disqualification. The Exchange proposed to replace this provision to provide that at each annual meeting of the stockholders, the stockholders will elect directors to serve until the next annual meeting or until their successors are elected and qualified.53 The Exchange also proposed that the Board shall appoint the Chairman of the Board by majority vote, and that each director shall hold office for a term that expires at the annual meeting of the stockholders next following his or her election, provided that if he or she is not re-elected and his or her successor is not elected and qualified at the meeting and there remains a vacancy on the Board, he or she shall continue to serve until his or her successor is elected and qualified or until his or her earlier death, resignation, or removal.54 The CHX Bylaws also would provide that a director may serve for any number of terms, consecutive or otherwise.55 The Exchange represented that the change from a three-class board with staggered terms to a board with one class of directors elected annually would make the organization of the Board consistent with those of all of the NYSE Exchanges.56

The Exchange proposed that except as otherwise provided in the CHX Bylaws or the Exchange's rules, the shareholder shall nominate directors for election at the annual meeting of the shareholder, which nominations shall comply with

 $^{^{\}rm 44}\,\rm Article~X$ of the proposed CHX Holdings Certificate.

⁴⁵ Article XII of the proposed CHX Holdings Certificate and Section 7.9(b) of the proposed CHX Holdings Bylaws.

^{46 15} U.S.C. 78t(a).

^{47 15} U.S.C. 78t(e).

^{48 15} U.S.C. 78u-3.

⁴⁹ See Notice, supra note 4, at 24520.

 $^{^{50}\,}See$ proposed CHX Bylaws, Article II, Section 2(a).

⁵¹ *Id*.

⁵² See proposed CHX Bylaws, Article II, Section 2(b). The Exchange noted that proposed Article II, Sections 2(a) and (b) would be consistent with the NYSE National Bylaws and NYSE Arca Bylaws. See Notice, supra note 4, at 24521.

⁵³ See proposed CHX Bylaws, Article II, Section 2(c).

 $^{^{54}\,}See$ proposed CHX Bylaws, Article II, Section 2(d).

⁵⁵ *Id*.

⁵⁶ See Notice, supra note 4, at 24522.

the Exchange's rules and the CHX Bylaws.57

The Exchange also proposed to amend the CHX Bylaw provisions relating to the nomination and election of the Board to make these provisions similar to the provisions in the NYSE Arca and NYSE National Bylaws, subject to certain terms specific to the Exchange.58 Currently, the Nominating and Governance Committee ("NGC") of the Exchange consists of two Public Directors and two Original STP Participant Directors, one of whom must not be a representative of a firm that is a holder of Series A Preferred Stock of CHX Holdings. The NGC also is currently appointed by the Board. The Exchange proposed that the Nominating Committee be composed solely of STP Participant Directors and/or Permit Holder representatives, and proposed to rename the NGC to the "Nominating Committee." 59

The Exchange also proposed to amend the provisions relating to the process for nominating candidates to the Board. Currently, the Bylaws provide that each year the NGC shall nominate persons who will qualify as Participant Directors pursuant to the procedures set forth in the Bylaws. The Exchange proposed to adopt a new process for nominating nominees to the Board. Specifically, pursuant to Article II, Section 3(b) of the CHX Bylaws, CHX proposed that the Nominating Committee shall publish the name(s) of one or more Participants as its nominee(s) for STP Participant Directors of the Board. The Nominating Committee would name sufficient nominees so that at least 20 percent of the directors consist of STP Participant Directors, and the names of the nominees shall be published on a date in each year sufficient to accommodate the process described ("Announcement Date"). After the name of the proposed nominee(s) is published, the CHX Bylaws allow Permit Holders in good standing to submit a petition to the Exchange in writing to nominate additional eligible candidate(s) to fill STP Participant Director position(s) during the next term. If a written petition of at least 10 percent of Permit Holders in good standing is submitted to the Nominating Committee within two weeks after the Announcement Date, such person(s) would also be nominated by the Nominating Committee,

provided, however, that no Permit Holder, either alone or together with other Permit Holders that are deemed its affiliates, may account for more than 50 percent of the signatories to the petition endorsing a particular petition nominee for the STP Participant Director position(s) on the Board. Article 2, Section 3(b) of the CHX Bylaws would stipulate that each petition for a petition candidate must include a completed questionnaire used to gather information concerning director candidates, with the form of the questionnaire provided by the Exchange upon the request of any Permit Holder. The same provision also provides that, notwithstanding anything to the contrary, the Nominating Committee shall determine whether any petition candidate is eligible to serve on the Board (including whether such person is free of any statutory disqualification), and such determination shall be final and conclusive.

In Article II, Section 3(c) of the CHX Bylaws, the Exchange also proposed a petition election process in the event that the number of nominees exceeds the number of available seats. In this case, the Nominating Committee shall submit the contested nomination to the Permit Holders for selection. Permit Holders would be afforded a confidential voting procedure and be given no less than 20 calendar days to submit their votes. A Permit Holder in good standing may select one nominee for the contested seat on the Board; provided, however that no Permit Holder, either alone or together with other Permit Holders who are deemed its affiliates, may account for more than 20 percent of the votes cast for a particular nominee for the STP Participant Director position(s) on the Board. With respect to the contested position, the Exchange proposed that the nominee for the Board receiving the most votes of Permit Holders shall be submitted by the Nominating Committee to the Board and that the Nominating Committee shall also submit uncontested nominees to the Board, and tie votes shall be decided by the Board at its first meeting following the election. Finally, the Exchange proposed that the Board shall appoint the Nominating Committee. 60

The Exchange also proposed to amend Article II, Section 6 of the current CHX Bylaws, which addresses how vacancies on the Board shall be filled. Currently, this provision provides that any vacancy on the Board due to "the death, retirement, resignation, disqualification

or removal of a director" or to an increase in the number of directors between annual meetings "shall be filled only with a person nominated by the Chairman and Vice Chairman of the Corporation and elected by a majority of the directors then in office, though less than a quorum or by a sole remaining director," with the caveat that, when stockholders remove a director from office for cause, the stockholders may fill the vacancy at the same meeting.

The Exchange proposed to revise this provision to also provide that vacancies also may be filled by action taken by the stockholders of the Exchange.61 Therefore, pursuant to the CHX Bylaws, vacancies on the Board may be filled (i) with a person nominated by the Chairman and Vice Chairman of the Exchange and elected by a majority of the directors then in office, though less than a quorum or by a sole remaining director, or (ii) by action taken by the stockholders of the Exchange. As a result, CHX Holdings, as the stockholder of the Exchange, would be able to fill vacancies on the Board, include any that exist following the Transaction. The Exchange represented that this provision would be consistent with the bylaws of NYSE Arca and NYSE National, as well as the bylaws of other SROs, such as CBOE Exchange, Inc. and CBOE BYX Exchange, Inc. 62

Finally, the Exchange proposed to restructure and amend Article FIFTH of the CHX Certificate governing the composition, nomination and election of its Board to more closely align with the proposed amended CHX Bylaws and the relevant provisions of the other NYSE Exchanges, to make certain administrative and conforming

changes.63

In addition, the Exchange has proposed to amend CHX Article 2, Rules 2, 3, 4, and 11, to conform with proposed changes to the CHX Bylaws and CHX Certificate related to the Exchange Board, which are discussed above, and to reduce the minimum size of the Board's Executive, Finance, and Regulatory Oversight Committees to three members, conforming the committee size to the governing documents of the NYSE Exchanges, all of which provide that their respective regulatory oversight committees consist of three directors.

The Commission believes that the proposed changes to the CHX Bylaws and CHX Certificate related to the number, composition, term of office, and qualifications of the Board are

⁵⁷ See proposed CHX Bylaws, Article II, Section 2(f). According to the Exchange, this provision would be consistent with the NYSE National Bylaws and NYSE Arca Bylaws. See Notice, supra note 4, at 24522.

 $^{^{58}}$ See Notice, supra note 4, at 24522.

⁵⁹ See proposed CHX Bylaws, Article II, Section

⁶⁰ See proposed CHX Bylaws, Article II, Section

⁶¹ See Amendment No. 2, supra note 5, at 4.

⁶² See Amendment No. 2, supra note 5, at 3.

⁶³ See Notice, supra note 4, at 24523-24.

consistent with Section 6(b)(3) of the Exchange Act in that they assure the fair representation of CHX members on the CHX Board, and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer. In particular, the Commission finds that the requirements that at least 20 percent of the Board be comprised of STP Participant Directors and 50 percent of the Board be comprised of Public Directors are consistent with the requirements of Section 6(b)(3). In addition, the Commission finds that the proposed provisions of the CHX Bylaws and CHX Certificate relating to the number, term of office, and qualifications of the Board are consistent with Section 6(b)(1) of the Exchange Act in that they are designed to assist the Exchange in fulfilling its self-regulatory obligations and administering and complying with the requirements of the Exchange Act.

5. Miscellaneous Changes to Organizational Document

The Exchange has proposed to make non-substantive technical and conforming changes throughout the CHX Certificate and CHX Bylaws to reflect the Exchange's new ownership, including updating corporate names, defined terms, and cross-references. In addition, the Exchange has proposed to amend the ICE Independence Policy to reflect the change in ownership of the Exchange and to provide similar protections to the Exchange as are currently provided to the NYSE Exchanges by the policy. In addition, the Exchange has proposed to remove outdated or obsolete references.

The Commission believes that these amendments are consistent with the Exchange Act as they are technical in nature. They do not alter any of the restrictions contained in CHX Certificate or CHX Bylaws. The amendments merely update such governing documents to reflect the new ownership of the Exchange.

6. Inbound Router

The Exchange states that upon Closing, Archipelago Securities, LLC ("ArcaSec"), a Participant of the Exchange and wholly-owned subsidiary of NYSE Group, will become an affiliate of the Exchange. CHX Article 3, Rule 20 provides that a Participant shall not be or become an affiliate of the Exchange, or an affiliate of any affiliate of the Exchange, in the absence of an effective filing under Section 19(b) of the

Exchange Act. ⁶⁴ The Exchange represents that the Exchange and ArcaSec will each operate in essentially the same manner upon Closing as it operates today, and that therefore, upon the Closing, ArcaSec will not operate as a "facility" of the Exchange, as defined under Section 3(a)(2) of the Exchange Act, ⁶⁵ and will continue to act, and be regulated by the Exchange, as a Participant on the same terms as any other Participant, apart from CHXBD.

The Exchange has proposed to add a new subparagraph (b) to CHX Article 19, Rule 2 to provide that ArcaSec may act as an inbound router, and to impose certain limitations and conditions to ArcaSec's affiliation with the Exchange to permit the Exchange to accept inbound orders that ArcaSec routes. Specifically, proposed Rule 2(b)(1) would provide that, for so long as the Exchange is affiliated with the NYSE Exchanges and ArcaSec, in its capacity as a facility of the NYSE Exchanges, is utilized for the routing of any approved types of orders from those exchanges to the Exchange (such function of ArcaSec is referred to as the "Inbound Router"), each of the Exchange and ArcaSec shall undertake as follows: (1) The Exchange shall maintain an agreement pursuant to Rule 17d-2 under the Exchange Act ("Rule 17d–2 Plan") with a nonaffiliated SRO to relieve the Exchange of regulatory responsibilities for ArcaSec with respect to rules that are common rules between the Exchange and the non-affiliated SRO; 66 (2) the Exchange shall maintain a regulatory services agreement ("RSA") with a non-affiliated SRO to perform regulatory responsibilities for ArcaSec for unique Exchange rules; (3) the RSA shall require the Exchange and the nonaffiliated SRO to monitor ArcaSec for compliance with the Exchange's trading rules, and collect and maintain, in an easily accessible manner, all alerts, complaints, investigations and enforcement actions (collectively "Exceptions") in which ArcaSec (in routing orders to the Exchange) is identified as a participant that has potentially violated applicable Exchange or Commission rules. The RSA shall require that the non-affiliated SRO provide a report, at least quarterly, to the Chief Regulatory Officer of the Exchange quantifying all Exceptions; (4) the Exchange, on behalf of the holding company owning both the Exchange and ArcaSec, shall establish and maintain procedures and internal controls

reasonably designed to prevent ArcaSec from receiving any benefit, taking any action or engaging in any activity based on non-public information regarding planned changes to Exchange systems, obtained as a result of its affiliation with the Exchange, until such information is available generally to similarly situated Participants of the Exchange in connection with the provision of inbound order routing to the Exchange; and (5) the Exchange may furnish to ArcaSec the same information on the same terms that the Exchange makes available in the normal course of business to any other Participant. Proposed Rule 2(b)(2) would state that, provided the above conditions are complied with, ArcaSec may provide inbound routing services to the Exchange from the NYSE Exchanges.⁶⁷

In the past, the Commission has expressed concern that the affiliation of an exchange with one of its members raises potential conflicts of interest and the potential for unfair competitive advantage. 68 Although the Commission continues to be concerned about potential unfair competition and conflicts of interest between an exchange's self-regulatory obligations and its commercial interest when the exchange is affiliated with one of its members, the Commission believes that it is consistent with the Exchange Act to permit ArcaSec, in its capacity as a facility of each of the NYSE Exchanges, to route orders inbound to the Exchange, subject to the limitations and conditions described above. 69 The Commission believes that the limitations and conditions in CHX Article 19, Rule 2(b) will mitigate its concerns about potential conflicts of interest and unfair competitive advantage. In particular, the

⁶⁴ 15 U.S.C. 78s(b).

^{65 15} U.S.C. 78c(a)(2).

 $^{^{66}}$ "Common rules" would be defined in the Rule 17d–2 Plan.

 $^{^{67}}$ The Exchange will ensure a Rule 17d–2 Plan is in place and comply with the other listed conditions prior to ArcaSec acting as an Inbound Router of the Exchange.

⁶⁸ See, e.g., Securities Exchange Act Release Nos. 53382 (February 27, 2006), 71 FR 11251 (March 6, 2006) (SR-NYSE-2005-77) (order approving the combination of the New York Stock Exchange, Inc. and Archipelago Holdings, Inc.); 58673 (September 29, 2008), 73 FR 57707 (October 3, 2008) (SR Amex-2008-62 and SR-NYSE-2008-60) (order approving the combination of NYSE Euronext and the American Stock Exchange LLC); 59281 (January 22, 2009), 74 FR 5014 (January 28, 2009) (SR NYSE-2008-120) (order approving a joint venture between NYSE and BIDS Holdings L.P.); 61698 (March 12, 2010), 75 FR 13151 (March 18, 2010) (File Nos. 10-194 and 10-196) (order granting the exchange registration of EDGX Exchange, Inc. and EDGA Exchange, Inc.); and 62716 (August 13, 2010), 75 FR 51295 (August 19, 2010) (File No. 10-198) (order granting the exchange registration of BATS-Y Exchange, Inc.).

⁶⁹The Commission notes that the proposed conditions are similar to those of other NYSE Exchanges. See NYSE Arca Rule 7.45–E(c), NYSE Rule 17(c)(2), and NYSE American Rule 7.45E(c).

Commission believes that the Rule 17d–2 Plan, RSA, and Exception reporting requirements, procedures, and internal controls would help protect the independence of the Exchange's self-regulatory function with respect to ArcaSec. The Commission also believes that the proposed rule is designed to prevent ArcaSec from acting on non-public information obtained as a result of its affiliation with the Exchange, and that the proposed changes are consistent with the Exchange Act.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the Amendment Nos. 2 and 3 to the proposed rule change is consistent with the Exchange 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–CHX–2018–004 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-CHX-2018-004. 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 website (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 website 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. Persons submitting comments are

cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CHX–2018–004, and should be submitted on or before August 9, 2018.

IV. Accelerated Approval of Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3

The Commission finds good cause to approve the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 prior to the 30th day after the date of publication of notice of Amendments Nos. 2 and 3 in the Federal Register. As noted above, Amendment Nos. 2 and 3 do not change the structure or purpose of the proposed rule change as it was previously published for notice and comment.⁷⁰ The Commission believes that an additional notice and comment period for Amendment Nos. 2 and 3 before approval of the proposed rule change would not be in furtherance of the public interest or the protection of investors. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Exchange Act,71 to approve the proposed rule change, as modified by Amendment Nos. 1, 2, and 3, on an accelerated basis.

V. Conclusion

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendments Nos. 1, 2, and 3 is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act ⁷² that the proposed rule change (SR–CHX–2018–004), as modified by Amendments Nos. 1, 2, and 3, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 7^3

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15370 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17f–6; SEC File No. 270–392, OMB Control No. 3235–0447

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 17f–6 (17 CFR 270.17f–6) under the Investment Company Act of 1940 (15 U.S.C. 80a) permits registered investment companies ("funds") to maintain assets (i.e., margin) with futures commission merchants ("FCMs") in connection with commodity transactions effected on both domestic and foreign exchanges. Before the rule was adopted, funds generally were required to maintain such assets in special accounts with a custodian bank.

The rule requires a written contract that contains certain provisions designed to ensure important safeguards and other benefits relating to the custody of fund assets by FCMs. To protect fund assets, the contract must require that FCMs comply with the segregation or secured amount requirements of the Commodity Exchange Act ("CEA") and the rules under that statute. The contract also must contain a requirement that FCMs obtain an acknowledgment from any clearing organization that the fund's assets are held on behalf of the FCM's customers according to CEA provisions.

Because rule 17f–6 does not impose any ongoing obligations on funds or FCMs, Commission staff estimates there are no costs related to *existing* contracts between funds and FCMs. This estimate does not include the time required by an FCM to comply with the rule's contract requirements because, to the extent that complying with the contract provisions could be considered "collections of information," the burden hours for compliance are already included in other PRA submissions.¹

 $^{^{70}\,}See\,supra$ notes 5 and 6.

⁷¹ 15 U.S.C. 78s(b)(2).

^{72 15} U.S.C. 78s(b)(2).

^{73 17} CFR 200.30-3(a)(12).

¹The rule requires a contract with the FCM to contain two provisions requiring the FCM to comply with existing requirements under the CEA

Thus, Commission staff estimates that any burden of the rule would be borne by funds and FCMs entering into *new* contracts pursuant to the rule. Commission staff estimates that approximately 214 fund complexes and 2,825 funds currently effect commodities transactions and could deposit margin with FCMs in connection with those transactions pursuant to rule 17f–6.² Staff further estimates that of this number, 21 fund complexes and 283 funds enter into new contracts with FCMs each year.³

Based on conversations with fund representatives, Commission staff understands that fund complexes typically enter into contracts with FCMs on behalf of all funds in the fund complex that engage in commodities transactions. Funds covered by the contract are typically listed in an attachment, which may be amended to encompass new funds. Commission staff estimates that the burden for a fund complex to enter into a contract with an FCM that contains the contract requirements of rule 17f-6 is one hour, and further estimates that the burden to add a fund to an existing contract between a fund complex and an FCM is 6 minutes.

Accordingly, Commission staff estimates that funds and FCMs spend 49 burden hours annually complying with the information collection requirements of rule 17f–6.4 These estimates are made solely for the purposes of the Paperwork Reduction Act, and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules and forms.

Compliance with the collection of information requirements of the rule is necessary to obtain the benefit of relying on the rule. 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.

and rules adopted thereunder. Thus, to the extent these provisions could be considered collections of information, the hours required for compliance would be included in the collection of information burden hours submitted by the CFTC for its rules.

The public may view the background documentation for this information collection at the following website, 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 Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15374 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17a–6, SEC File No. 270–433, OMB Control No. 3235–0489

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (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 extension of the previously approved collection of information provided for in Rule 17a–6 (17 CFR 240.17a–6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.).

Rule 17a–6 permits national securities exchanges, national securities associations, registered clearing agencies, and the Municipal Securities Rulemaking Board ("MSRB") (collectively, "SROs") to destroy or convert to microfilm or other recording media records maintained under Rule 17a–1, if they have filed a record destruction plan with the Commission and the Commission has declared such plan effective.

There are currently 32 SROs: 21 national securities exchanges, 1 national securities association, the MSRB, and 9 registered clearing agencies. Of the 32

SROs, only 2 SRO respondents have filed a record destruction plan with the Commission. The staff calculates that the preparation and filing of a new record destruction plan should take 160 hours. Further, any existing SRO record destruction plans may require revision, over time, in response to, for example, changes in document retention technology, which the Commission estimates will take much less than the 160 hours estimated for a new plan. The Commission estimates that each SRO that has filed a destruction plan will spend approximately 30 hours per year making required revisions. Thus, the total annual compliance burden is estimated to be 60 hours per year based on two respondents. The approximate compliance cost per hour is \$422, resulting in a total internal cost of compliance for these respondents of \$25,320 per year (60 hours @ \$422 per hour).

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 website: 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 Candace Kenner, 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 13, 2018.

Eduardo A. Aleman.

Assistant Secretary.

[FR Doc. 2018–15378 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Rule 17a–5(c); SEC File No. 270–199, OMB Control No. 3235–0199.

² This estimate is based on the number of funds that reported on Form N–SAR from June 1, 2017–November 30, 2017, in response to sub-items E through I of item 70, that they engaged in futures and commodity options transactions.

³These estimates are based on the assumption that 10% of fund complexes and funds enter into new FCM contracts each year. This assumption encompasses fund complexes and funds that enter into FCM contracts for the first time, as well as fund complexes and fund that change the FCM with whom they maintain margin accounts for commodities transactions.

 $^{^4}$ This estimate is based upon the following calculation: (21 fund complexes $\times\,1$ hour) + (283 funds $\times\,0.1$ hours) = 49 hours.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (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 previously approved collection of information provided for in Rule 17a–5(c), (17 CFR 240.17a–5(c)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.).

Rule 17a–5(c) generally requires broker-dealers who carry customer accounts to provide statements of the broker-dealer's financial condition to their customers. Paragraph (c)(5) of Rule 17a–5 provides a conditional exemption from this requirement. A broker-dealer that elects to take advantage of the exemption must publish its statements on its website in a prescribed manner, and must maintain a toll-free number that customers can call to request a copy of the statements.

The purpose of the Rule is to ensure that customers of broker-dealers are provided with information concerning the financial condition of the firm that may be holding the customers' cash and securities. The Commission, when adopting the Rule in 1972, stated that the goal was to "directly" send a customer essential information so that the customer could "judge whether his broker or dealer is financially sound." The Commission adopted the Rule in response to the failure of several brokerdealers holding customer funds and securities in the period between 1968 and 1971.

The Commission estimates that approximately 162 broker-dealer respondents carrying approximately 132 million public customer accounts incur a burden of approximately 161,037 hours per year to comply with the Rule.

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 website: 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 Candace Kenner, 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 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15375 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736.

Extension:

Rule 6c–7; SEC File No. 270–269, OMB Control No. 3235–0276.

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 (the "Commission") has submitted to the Office of Management and Budget a request for extension of the previously approved collection of information discussed below.

Rule 6c-7 (17 CFR 270.6c-7) under the Investment Company Act of 1940 (15 U.S.C. 80a-1 et seq.) ("1940 Act") provides exemption from certain provisions of Sections 22(e) and 27 of the 1940 Act for registered separate accounts offering variable annuity contracts to certain employees of Texas institutions of higher education participating in the Texas Optional Retirement Program. There are approximately 50 registrants governed by Rule 6c-7. The burden of compliance with Rule 6c-7, in connection with the registrants obtaining from a purchaser, prior to or at the time of purchase, a signed document acknowledging the restrictions on redeem ability imposed by Texas law, is estimated to be approximately 3 minutes per response for each of approximately 2300 purchasers annually (at an estimated \$66 per hour),¹ for a total annual burden of 115 hours (at a total annual cost of \$7,590).

Rule 6c–7 requires that the separate account's registration statement under the Securities Act of 1933 (15 U.S.C. 77a et seq.) include a representation that Rule 6c–7 is being relied upon and is being complied with. This requirement enhances the Commission's ability to monitor utilization of and compliance with the rule. There are no recordkeeping requirements with respect to Rule 6c–7.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. The Commission does not include in the estimate of average burden hours the time preparing registration statements and sales literature disclosure regarding the restrictions on redeem ability imposed by Texas law. The estimate of burden hours for completing the relevant registration statements are reported on the separate PRA submissions for those statements. (See the separate PRA submissions for Form N-3 (17 CFR 274.11b) and Form N-4 (17 CFR 274.11c).

Complying with the collection of information requirements of the rules is necessary to obtain a benefit. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number.

The public may view the background documentation for this information collection at the following website, 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 Candace Kenner, 100 F Street NE, Washington, DC 20549 or send an email to: PRA Mailbox@ sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: July 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15382 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

¹\$66/hour figure for a Compliance Clerk is based on the Commission's estimates concerning the allocation of burden hours and the relevant wage rates from the Commission's consultations with industry representatives and on salary information for the securities industry compiled by the Securities Industry and Financial Markets Association's Office Salaries in the Securities Industry 2013. The estimated wage figures are modified by Commission staff to account for an 1800-hour work-year and multiplied by 2.93 to account for bonuses, firm size, employee benefits, overhead, and adjusted to account for the effects of inflation. See Securities Industry and Financial Markets Association, Report on Management &

Professional Earnings in the Securities Industry

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83631; File No. SR–FICC–2017–022]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Amend the Loss Allocation Rules and Make Other Changes

July 13, 2018.

On December 18, 2017, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–FICC–2017–022 ("Proposed Rule Change") to amend the loss allocation rules and make other changes; the Proposed Rule Change was published for comment in the **Federal Register** on January 8, 2018. On February 8, 2018,

the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.2 On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change; on June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the Proposed Rule Change.³ On June 28, 2018, FICC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.4 As of the date of this release, the Commission has not received any comments on the Proposed Rule Change.

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by FICC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to FICC's Government Securities Division ("GSD") Rulebook ("GSD Rules") and Mortgage-Backed Securities Division ("MBSD" and, together with GSD, the "Divisions" and, each, a "Division") Clearing Rules ("MBSD Rules," and collectively with the GSD Rules, the "Rules") in order to amend provisions in the Rules regarding loss allocation as well as make other changes, as described in greater detail below.⁵

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of Amendment No. 1

This filing constitutes Amendment No. 1 ("Amendment") to rule filing SR–FICC–2017–022 ("Rule Filing") previously filed by FICC on December 18, 2017.⁶ This Amendment amends and replaces the Rule Filing in its entirety. FICC submits this Amendment in order to further clarify the operation of the proposed rule changes on loss allocation by providing additional information and examples. In particular, this Amendment would:

(i) Clarify which Tier One Netting Members and Tier One Members would be subject to loss allocation with respect to Defaulting Member Events (as defined below and in the proposed rule change) and Declared Non-Default Loss Events (as defined below and in the proposed rule change) occurring during an Event Period (as defined below and in the proposed rule change). Specifically, pursuant to the Amendment, proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that each Tier One Netting Member or Tier One Member, as applicable, that is a Tier One Netting Member or Tier One Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member (as defined below and in the proposed rule change)) and each Declared Non-Default Loss Event occurring during the Event Period. Proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would also make it clear

¹¹⁵ U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively. Securities Exchange Act Release No. 82427 (January 2, 2018), 83 FR 854 (January 8, 2018) (SR-FICC-2017-022). On December 18, 2017, FICC filed the Proposed Rule Change as advance notice SR-FICC-2017-806 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release No. 82583 (January 24, 2018), 83 FR 4358 (January 30, 2018) (SR-FICC-2017-806). On April 10, 2018, the Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Commission's Request for Additional Information," available at http:// $www.sec.gov/rules/sro/ficc-an.shtml. \ {\tt On June 28},$ 2018, FICC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, FICC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/ficc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(E) and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at http://www.sec.gov/

rules/sro/ficc-an.shtml. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

Securities Exchange Act Release No. 82670
 (February 8, 2018), 83 FR 6626 (February 14, 2018)
 (SR-DTC-2017-022; SR-FICC-2017-022; SR-NSCC-2017-018)

³ Securities Exchange Act Release No. 82909 (March 20, 2018), 83 FR 12990 (March 26, 2018) (SR–FICC–2017–022); Securities Exchange Act Release No. 83510 (June 25, 2018), 83 FR 30791 (June 29, 2018) (SR–DTC–2017–022; SR–FICC–2017–022; SR–NSCC–2017–018).

⁴To promote the public availability and transparency of its post-notice amendment, FICC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the Commission's website at https://www.sec.gov/rules/sro/ficc.htm and thus been publicly available since June 29, 2018.

⁵ Capitalized terms not defined herein are defined in the GSD Rules, *available at http://*

www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_gov_rules.pdf, and the MBSD Rules, available at www.dtcc.com/~/media/Files/Downloads/legal/rules/ficc_mbsd_rules.pdf.

⁶ See Securities Exchange Act Release No. 82427 (January 2, 2018), 83 FR 854 (January 8, 2018) (SR-FICC-2017-022).

that any Tier One Netting Member or Tier One Member, as applicable, for which FICC ceases to act on a non-Business Day, triggering an Event Period that commences on the next Business Day, would be deemed to be a Tier One Netting Member or Tier One Member, as applicable, on the first day of that Event Period.

(ii) Clarify the obligations and Loss Allocation Cap (as defined below and in the proposed rule change) of a Tier One Netting Member or a Tier One Member, as applicable, that withdraws from membership in respect of a loss allocation round. Specifically, pursuant to the Amendment, proposed Section 7b of GSD Rule 4 and MBSD Rule 4 would provide that the Tier One Netting Member or Tier One Member, as applicable, would nevertheless remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under GSD Rule 4 or MBSD Rule 4, as applicable; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap as fixed in the round for which it withdrew.

(iii) Clarify that a member would be obligated to FICC for all losses and liabilities incurred by FICC arising out of or relating to any Defaulting Member Event with respect to the member. Specifically, pursuant to the Amendment, proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that each member would be obligated to FICC for the entire amount of any loss or liability incurred by FICC arising out of or relating to any Defaulting Member Event with respect to such member.

(iv) Clarify that, although a Defaulting Member would not be allocated a ratable share of losses and liabilities arising out of or relating to its own Defaulting Member Event, it would remain obligated to FICC for all such losses and liabilities. Specifically, pursuant to the Amendment, proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that no loss allocation under GSD Rule 4 or MBSD Rule 4, as applicable, would constitute a waiver of any claim FICC may have against a GSD Member or MBSD Member, as applicable, for any loss or liability to which the GSD Member or MBSD Member is subject under the GSD Rules or MBSD Rules, as applicable, including, without limitation, any loss or liability to which it may be subject under GSD Rule 4 or MBSD Rule 4, as applicable.

In addition, pursuant to the Amendment, FICC is making other clarifying and technical changes to the proposed rule change, as proposed herein.

Nature of the Proposed Change

The primary purpose of this proposed rule change is to amend GSD's and MBSD's loss allocation rules in order to enhance the resiliency of the Divisions' loss allocation processes so that each Division can take timely action to address multiple loss events that occur in succession during a short period of time (defined and explained in detail below). In connection therewith, the proposed rule change would (i) align the loss allocation rules of the three clearing agencies of The Depository Trust & Clearing Corporation ("DTCC"), namely The Depository Trust Company ("DTC"), National Securities Clearing Corporation ("NSCC"), and FICC (collectively, the "DTCC Clearing Agencies"), so as to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies, (ii) increase transparency and accessibility of the loss allocation rules by enhancing their readability and clarity, (iii) amend language regarding FICC's use of MBSD Clearing Fund, and (iv) make conforming and technical changes.

(i) Background

Central counterparties ("CCPs") play a key role in financial markets by mitigating counterparty credit risk on transactions between market participants. CCPs achieve this by providing guaranties to participants and, as a consequence, are typically exposed to credit risks that could lead to default losses. In addition, in performing its critical functions, a CCP could be exposed to non-default losses that are otherwise incident to the CCP's clearance and settlement business.

A CCP's rulebook should provide a complete description of how losses would be allocated to participants if the size of the losses exceeded the CCP's pre-funded resources. Doing so provides for an orderly allocation of losses, and potentially allows the CCP to continue providing critical services to the market and thereby results in significant financial stability benefits. In addition, a clear description of the loss allocation process offers transparency and accessibility to the CCP's participants.

Current FICC Loss Allocation Process

As CCPs, FICC's Divisions' loss allocation processes are key components of their respective risk management processes. Risk management is the foundation of FICC's ability to guarantee settlement in each Division, as well as

the means by which FICC protects itself and its members from the risks inherent in the clearance and settlement process. FICC's risk management processes must account for the fact that, in certain extreme circumstances, the collateral and other financial resources that secure FICC's risk exposures may not be sufficient to fully cover losses resulting from the liquidation of the portfolio of a member for whom a Division has ceased to act.⁷

The GSD Rules and the MBSD Rules each currently provide for a loss allocation process through which both FICC (by applying up to 25% of its retained earnings in accordance with Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4) and its members would share in the allocation of a loss resulting from the default of a member for whom a Division has ceased to act pursuant to the Rules. The GSD Rules and the MBSD Rules also recognize that FICC may incur losses outside the context of a defaulting member that are otherwise incident to each Division's clearance and settlement business.

The current GSD and MBSD loss allocation rules provide that, in the event the Division ceases to act for a member, the amounts on deposit to the Clearing Fund from the defaulting member, along with any other resources of, or attributable to, the defaulting member that FICC may access under the GSD Rules or the MBSD Rules (e.g., payments from Cross-Guaranty Agreements), are the first source of funds the Division would use to cover any losses that may result from the closeout of the defaulting member's guaranteed positions. If these amounts are not sufficient to cover all losses incurred, then each Division will apply the following available resources, in the following loss allocation waterfall order:

First, as provided in the current Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4, FICC's corporate contribution of up to 25 percent of FICC's retained earnings existing at the time of the failure of a defaulting member to fulfill its obligations to FICC,

⁷ GSD is permitted to cease to act for (i) a GSD Member pursuant to GSD Rule 21 (Restrictions on Access to Services) and GSD Rule 22 (Insolvency of a Member), (ii) a Sponsoring Member pursuant to Section 14 and Section 16 of GSD Rule 3A (Sponsoring Members and Sponsored Members), and (iii) a Sponsored Member pursuant to Section 13 and Section 15 of GSD Rule 3A (Sponsoring Members and Sponsored Members). MBSD is permitted to cease to act for an MBSD Member pursuant to MBSD Rule 14 (Restrictions on Access to Services) and MBSD Rule 16 (Insolvency of a Member). GSD Rule 22A (Procedures for When the Corporation Ceases to Act) and MBSD Rule 17 (Procedures for When the Corporation Ceases to Act) set out the types of actions FICC may take when it ceases to act for a member. Supra note 5.

or such greater amount as the Board of Directors may determine; and

Second, if a loss still remains, use of the Clearing Fund of the Division and assessing the Division's Members in the manner provided in GSD Rule 4 and MBSD Rule 4, as the case may be. Specifically, FICC will divide the loss ratably between Tier One Netting Members and Tier Two Members with respect to GSD, or between Tier One Members and Tier Two Members with respect to MBSD, based on original counterparty activity with the defaulting member. Then the loss allocation process applicable to Tier One Netting Members or Tier One Members, as applicable, and Tier Two Members will proceed in the manner provided in GSD Rule 4 and MBSD Rule 4, as the case may be.

Špecifically, the applicable Division will first assess each Tier One Netting Member or Tier One Member, as applicable, an amount up to \$50,000, in an equal basis per such member. If a loss remains, the Division will allocate the remaining loss ratably among Tier One Netting Members or Tier One Members, as applicable, in accordance with the amount of each Tier One Netting Member's or Tier One Member's, as applicable, respective average daily Required Fund Deposit over the prior twelve (12) months. If a Tier One Netting Member or Tier One Member, as applicable, did not maintain a Required Fund Deposit for twelve (12) months, its loss allocation amount will be based on its average daily Required Fund Deposit over the time period during which such member did maintain a Required Fund Deposit.

Pursuant to current Section 7(g) of GSD Rule 4 and MBSD Rule 4, if, as a result of the Division's application of the Required Fund Deposit of a member, a member's actual Clearing Fund deposit is less than its Required Fund Deposit, it will be required to eliminate such deficiency in order to satisfy its Required Fund Deposit amount. In addition to losses that may result from the closeout of the defaulting member's guaranteed positions, Tier One Netting Members or Tier One Members, as applicable, can also be assessed for nondefault losses incident to each Division's clearance and settlement business, pursuant to current Section 7(f) of GSD Rule 4 and MBSD Rule 4.

The Rules of both Divisions currently provide that Tier Two Members are only subject to loss allocation to the extent they traded with the defaulting member and their trades resulted in a liquidation loss. FICC will assess Tier Two Members ratably based on their loss as a percentage of the entire remaining loss

attributable to Tier Two Members.8 Tier Two Members are required to pay their loss allocation obligations in full and replenish their Required Fund Deposits as needed and as applicable. The current Rule provisions which provide for loss allocation of non-default losses incident to each Division's clearance and settlement business (i.e., Section 7(f) of GSD Rule 4 and MBSD Rule 4) do not apply to Tier Two Members.

Overview of the Proposed Rule Changes A. Changes To Enhance Resiliency of GSD's and MBSD's Loss Allocation Processes

In order to enhance the resiliency of GSD's and MBSD's loss allocation processes, FICC proposes to change the manner in which each of the aspects of the loss allocation waterfall described above would be employed. GSD and MBSD would retain the current core loss allocation process following the application of the defaulting member's resources, i.e., first, by applying FICC's corporate contribution, and second, by pro rata allocations to Tier One Netting Members or Tier One Members, as applicable, and Tier Two Members. However, GSD and MBSD would clarify or adjust certain elements and introduce certain new loss allocation concepts, as further discussed below. The proposal would also retain the types of losses that can be allocated to Tier One Netting Members or Tier One Members, as applicable, and Tier Two Members as stated above. In addition, the proposed rule change would address the loss allocation process as it relates to losses arising from or relating to multiple default or non-default events in a short period of time, also as described below.

Accordingly, FICC is proposing five (5) key changes to enhance each Division's loss allocation process:

(1) Changing the Calculation and Application of FICC's Corporate Contribution

As stated above, Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4 currently provide that FICC will contribute up to 25% of its retained earnings (or such higher amount as the Board of Directors shall determine) to a loss or liability that is not satisfied by the defaulting member's Clearing Fund

deposit. Under the proposal, FICC would amend the calculation of its corporate contribution from a percentage of its retained earnings to a mandatory amount equal to 50% of the FICC General Business Risk Capital Requirement.⁹ FICC's General Business Risk Capital Requirement, as defined in FICC's Clearing Agency Policy on Capital Requirements, 10 is, at a minimum, equal to the regulatory capital that FICC is required to maintain in compliance with Rule 17Ad-22(e)(15) under the Act.¹¹ The proposed Corporate Contribution (as defined below and in the proposed rule change) would be held in addition to FICC's General Business Risk Capital Requirement.

Currently, the Rules do not require FICC to contribute its retained earnings to losses and liabilities other than those from member defaults. Under the proposal, FICC would apply its corporate contribution to non-default losses as well. The proposed Corporate Contribution would apply to losses arising from Defaulting Member Events and Declared Non-Default Loss Events (as such terms are defined below and in the proposed rule change), and would be a mandatory contribution by FICC prior to any allocation of the loss among the applicable Division's members. 12 As proposed, if the Corporate Contribution is fully or partially used against a loss or liability relating to an Event Period by one or both Divisions, the Corporate Contribution would be reduced to the remaining unused amount, if any, during the following two hundred fifty (250) Business Days in order to permit FICC to replenish the Corporate Contribution. 13 To ensure transparency,

Continued

⁸ GSD Rule 3B, Section 7 (Loss Allocation Obligations of CCIT Members) provides that CCIT Members will be allocated losses as Tier Two Members and will be responsible for the total amount of loss allocated to them. With respect to CCIT Members with a Joint Account Submitter, loss allocation will be calculated at the Joint Account level and then applied pro rata to each CCIT Member within the Joint Account based on the trade settlement allocation instructions. Supra note

⁹ FICC calculates its General Business Risk Capital Requirement as the amount equal to the greatest of (i) an amount determined based on its general business profile, (ii) an amount determined based on the time estimated to execute a recovery or orderly wind-down of FICC's critical operations, and (iii) an amount determined based on an analysis of FICC's estimated operating expenses for a six (6) month period.

¹⁰ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR-FICC-2017-007)

^{11 17} CFR 240.17Ad-22(e)(15).

¹² The proposed rule change would not require a Corporate Contribution with respect to the use of each Division's Clearing Fund as a liquidity resource: however, if FICC uses a Division's Clearing Fund as a liquidity resource for more than 30 calendar days, as set forth in proposed Section 5 of GSD Rule 4 and MBSD Rule 4, then FICC would have to consider the amount used as a loss to the respective Division's Clearing Fund incurred as a result of a Defaulting Member Event and allocate the loss pursuant to proposed Section 7 of Rule 4, which would then require the application of FICC's Corporate Contribution.

¹³ FICC believes that two hundred and fifth (250) Business Days would be a reasonable estimate of

all GSD Members and MBSD Members would receive notice of any such reduction to the Corporate Contribution. There would be one FICC Corporate Contribution, the amount of which would be available to both Divisions and would be applied against a loss or liability in either Division in the order in which such loss or liability occurs, i.e., FICC would not have two separate Corporate Contributions, one for each Division. In the event of a loss or liability relating to an Event Period, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, attributable to only one Division, the Corporate Contribution would be applied to that Division up to the amount then available. If a loss or liability relating to an Event Period, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, occurs simultaneously at both Divisions, the Corporate Contribution would be applied to the respective Divisions in the same proportion that the aggregate Average RFDs (as defined below and in the proposed rule change) of all members in that Division bear to the aggregate Average RFDs of all members in both Divisions.14

As compared to the current approach of applying "up to" a percentage of retained earnings to defaulting member losses, the proposed Corporate Contribution would be a fixed percentage of FICC's General Business Risk Capital Requirement, which would provide greater transparency and accessibility to members. The proposed Corporate Contribution would apply not only towards losses and liabilities arising out of or relating to Defaulting Member Events but also those arising out of or relating to Declared Non-Default Loss Events, which is consistent with the current industry guidance that "a CCP should identify the amount of its own resources to be applied towards losses arising from custody and investment risk, to bolster confidence

the time frame that FICC would require to replenish the Corporate Contribution by equity in accordance with FICC's Clearing Agency Policy on Capital Requirements, including a conservative additional period to account for any potential delays and/or unknown exigencies in times of distress.

that participants' assets are prudently safeguarded." ¹⁵

Under current Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4, FICC has the discretion to contribute amounts higher than the specified percentage of retained earnings, as determined by the Board of Directors, to any loss or liability incurred by FICC as result of the failure of a Defaulting Member to fulfill its obligations to FICC. This option would be retained and expanded under the proposal so that it would be clear that FICC can voluntarily apply amounts greater than the Corporate Contribution against any loss or liability (including non-default losses) of the Divisions, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation existing at the time.

The proposed rule changes relating to the calculation and application of Corporate Contribution are set forth in proposed Sections 7 and 7a of GSD Rule 4 and Sections 7 and 7a of MBSD Rule 4, as further described below.

(2) Introducing an Event Period

In order to clearly define the obligations of each Division and its respective Members regarding loss allocation and to balance the need to manage the risk of sequential loss events against members' need for certainty concerning their maximum loss allocation exposures, FICC is proposing to introduce the concept of an "Event Period" to the GSD Rules and the MBSD Rules to address the losses and liabilities that may arise from or relate to multiple Defaulting Member Events and/or Declared Non-Default Loss Events that arise in quick succession in a Division. Specifically, the proposal would group Defaulting Member Events and Declared Non-Default Loss Events occurring in a period of ten (10) Business Days ("Event Period") for purposes of allocating losses to Members of the respective Divisions in one or more rounds (as described below), subject to the limitations of loss allocation set forth in the proposed rule change and as explained below. 16 In the case of a loss or liability arising from or

relating to a Defaulting Member Event, an Event Period would begin on the day one or both Divisions notify their respective members that FICC has ceased to act 17 for the GSD Defaulting Member and/or the MBSD Defaulting Member (or the next Business Day, if such day is not a Business Day). In the case of a loss or liability arising from or relating to a Declared Non-Default Loss Event, an Event Period would begin on the day that FICC notifies members of the respective Divisions of the Declared Non-Default Loss Event (or the next Business Day, if such day is not a Business Day). If a subsequent Defaulting Member Event or Declared Non-Default Loss Event occurs during an Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period. An Event Period may include both Defaulting Member Events and Declared Non-Default Loss Events, and there would not be separate Event Periods for Defaulting Member Events or Declared Non-Default Loss Events occurring during overlapping ten (10) Business Day periods.

The amount of losses that may be allocated by each Division, subject to the required Corporate Contribution, and to which a Loss Allocation Cap would apply for any member that elects to withdraw from membership in respect of a loss allocation round, would include any and all losses from any Defaulting Member Events and any Declared Non-Default Loss Events during the Event Period, regardless of the amount of time, during or after the Event Period, required for such losses to be crystallized and allocated. 18

The proposed rule changes relating to the implementation of an Event Period are set forth in proposed Section 7 of GSD Rule 4 and Section 7 of MBSD Rule 4, as further described below.

(3) Introducing the Concept of "Rounds" and Loss Allocation Notice

Pursuant to the proposed rule change, a loss allocation "round" would mean a series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the sum of the Loss

¹⁴ FICC believes that if a loss or liability relating to an Event Period, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, occurs simultaneously at both Divisions, allocating the Corporate Contribution ratably between the two Divisions based on the aggregate Average RFDs of their respective members is appropriate because the aggregate Average RFDs of all members in a Division represent the amount of risks that those members bring to FICC over the look-back period of seventy (70) Business Days.

¹⁵ See Resilience of central counterparties (CCPs): Further guidance on the PFMI, issued by the Committee on Payments and Market Infrastructures and the International Organization of Securities Commissions, at 42 (July 2017), available at www.bis.org/cpmi/publ/d163.pdf.

¹⁶ FICC believes that having a ten (10) Business Day Event Period would provide a reasonable period of time to encompass potential sequential Defaulting Member Events or Declared Non-Default Loss Events that are likely to be closely linked to an initial event and/or a severe market dislocation episode, while still providing appropriate certainty for members concerning their maximum exposure to mutualized losses with respect to such events.

¹⁷ Supra note 7.

¹⁸ As discussed below, each Tier One Netting Member or Tier One Member, as applicable, that is a Tier One Netting Member or Tier One Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member) and each Declared Non-Default Loss Event occurring during the Event Period.

Allocation Caps of affected Tier One Netting Members or Tier One Members, as applicable (a "round cap"). When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. FICC may continue the loss allocation process in successive rounds until all losses from the Event Period are allocated among Tier One Netting Members or Tier One Members, as applicable, that have not submitted a Loss Allocation Withdrawal Notice (as defined below and in the proposed rule change) in accordance with proposed Section 7b of GSD Rule 4 or MBSD Rule

Each loss allocation would be communicated to Tier One Netting Members or Tier One Members, as applicable, by the issuance of a notice that advises the Tier One Netting Members or Tier One Members, as applicable, of the amount being allocated to them ("Loss Allocation Notice"). Each Tier One Netting Member's or Tier One Member's, as applicable, pro rata share of losses and liabilities to be allocated in any round would be equal to (i) the average of its Required Fund Deposit for the seventy (70) business days preceding the first day of the applicable Event Period or such shorter period of time that the member has been a member (each member's "Average RFD"), divided by (ii) the sum of Average RFD amounts of all members subject to loss allocation in such round.

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Tier One Netting Member or Tier One Member, as applicable, in that round has five (5) Business Days from the issuance of such first Loss Allocation Notice for the round to notify FICC of its election to withdraw from membership with GSD or MBSD, as applicable, pursuant to proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, and thereby benefit from its Loss Allocation Cap.¹⁹ The "Loss Allocation Cap" of a

Tier One Netting Member or Tier One Member, as applicable, would be equal to the greater of (x) its Required Fund Deposit on the first day of the applicable Event Period and (y) its Average RFD.

After a first round of loss allocations with respect to an Event Period, only Tier One Netting Members or Tier One Members, as applicable, that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, would be subject to further loss allocation with respect to that Event Period.

The amount of any second or subsequent round cap may differ from the first or preceding round cap because there may be fewer Tier One Netting Members or Tier One Members, as applicable, in a second or subsequent round if Tier One Netting Members or Tier One Members, as applicable, elect to withdraw from membership with GSD or MBSD, as applicable, as provided in proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, following the first Loss Allocation Notice in any round.

For example, for illustrative purposes only, after the required Corporate Contribution, if FICC has a \$5 billion loss determined with respect to an Event Period and the sum of Loss Allocation Caps for all Tier One Netting Members or Tier One Members, as applicable, subject to the loss allocation is \$4 billion, the first round would begin when FICC issues the first Loss Allocation Notice for that Event Period. FICC could issue one or more Loss Allocation Notices for the first round until the sum of losses allocated equals \$4 billion. Once the \$4 billion is allocated, the first round would end and FICC would need a second round in order to allocate the remaining \$1 billion of loss. FICC would then issue a Loss Allocation Notice for the \$1 billion and this notice would be the first Loss Allocation Notice for the second round. The issuance of the Loss Allocation

Notice for the \$1 billion would begin the second round.

The proposed rule change would link the Loss Allocation Cap to a round in order to provide Tier One Netting Members or Tier One Members, as applicable, the option to limit their loss allocation exposure at the beginning of each round. As proposed and as described further below, a Tier One Netting Member or Tier One Member, as applicable, could limit its loss allocation exposure to its Loss Allocation Cap by providing notice of its election to withdraw from membership within five (5) Business Days after the issuance of the first Loss Allocation Notice in any round.

The proposed rule changes relating to the implementation of "rounds" and Loss Allocation Notices are set forth in proposed Section 7 of GSD Rule 4 and Section 7 of MBSD Rule 4, as further described below.

(4) Implementing a Revised "Look-Back" Period To Calculate a Member's Loss Allocation Pro Rata Share and Its Loss Allocation Cap

Currently, the GSD Rules and the MBSD Rules calculate a Tier One Netting Member's or a Tier One Member's pro rata share for purposes of loss allocation based on the member's average daily Required Fund Deposit over the prior twelve (12) months (or such shorter period as may be available in the case of a member which has not maintained a deposit over such time period). The Rules currently do not anticipate the possibility of more than one Defaulting Member Event or Declared Non-Default Loss Event in quick succession.

GSD and MBSD are proposing to calculate each Tier One Netting Member's or Tier One Member's, as applicable, pro rata share of losses and liabilities to be allocated in any round (as described above and in the proposed rule change) to be equal to (i) the member's Average RFD divided by (ii) the sum of Average RFD amounts for all members that are subject to loss allocation in such round.

Additionally, as described above and in the proposed rule change, if a Tier One Netting Member or Tier One Member, as applicable, withdraws from membership pursuant to proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, GSD and MBSD are proposing that the member's Loss Allocation Cap be equal to the greater of (i) its Required Fund Deposit on the first day of the applicable Event Period or (ii) its Average RFD.

FICC believes that employing a revised look-back period of seventy (70)

¹⁹ Pursuant to current Section 7(g) of GSD Rule 4 and MBSD Rule 4, the time period for a member to give notice, pursuant to Section 13 of GSD Rule 3 and MBSD Rule 3, of its election to terminate its membership in GSD or MBSD, as applicable, in respect of an allocation arising from any Remaining Loss allocated by FICC pursuant to Section 7(d) of

GSD Rule 4 or Section 7(e) of MBSD Rule 4, as applicable, and any Other Loss, is the Close of Business on the Business Day on which the loss allocation payment is due to FICC. Current Section 13 of GSD Rule 4 and MBSD Rule 4 requires a 10-day notice period. *Supra* note 5.

FICC believes that it is appropriate to shorten such time period from 10 days to five (5) Business Days because FICC needs timely notice of which Tier One Netting Members or Tier One Members, as applicable, would remain in its membership for purpose of calculating the loss allocation for any subsequent round. FICC believes that five (5) Business Days would provide Tier One Netting Members or Tier One Members, as applicable, with sufficient time to decide whether to cap their loss allocation obligations by withdrawing from their membership in GSD or MBSD, as applicable.

Business Days instead of twelve (12) months to calculate a Tier One Netting Member's or a Tier One Member's, as applicable, loss allocation pro rata share and Loss Allocation Cap is appropriate, because FICC recognizes that the current look-back period of twelve (12) months is a very long period during which a member's business strategy and outlook could have shifted significantly, resulting in material changes to the size of its portfolios. A look-back period of seventy (70) Business Days would minimize that issue yet still would be long enough to enable FICC to capture a full calendar quarter of such members' activities and smooth out the impact from any abnormalities and/or arbitrariness that may have occurred.

The proposed rule changes relating to the implementation of the revised lookback period are set forth in proposed Section 7 of GSD Rule 4 and Section 7 of MBSD Rule 4, as further described below

(5) Capping Withdrawing Members' Loss Allocation Exposure and Related Changes

Currently, pursuant to Section 7(g) of GSD Rule 4 and MBSD Rule 4, a member can withdraw from membership in order to avail itself of a cap on loss allocation if the member notifies FICC via a written notice, in accordance with Section 13 of GSD Rule 3 or MBSD Rule 3, as applicable, of its election to terminate its membership. Such notice must be provided by the Close of Business on the Business Day on which the loss allocation payment is due to FICC and, if properly provided to FICC, would limit the member's liability for a loss allocation to its Required Fund Deposit for the Business Day on which the notification of allocation is provided to the member.²⁰ As discussed above, the proposed rule change would continue providing members the opportunity to limit their loss allocation exposure by offering withdrawal options; however, the cap on loss allocation would be calculated differently and the associated withdrawal process would also be modified as it relates to withdrawals associated with the loss allocation process. In particular, the proposed rule change would shorten the withdrawal notification period from 10 days to five (5) Business Days, as further described below.

As proposed, if a member timely provides notice of its withdrawal from membership in respect of a loss allocation round, the maximum amount of losses it would be responsible for would be its Loss Allocation Cap,²¹ provided that the member complies with the requirements of the withdrawal process in proposed Section 7b of GSD Rule 4 and Section 7b of MBSD Rule 4.

Currently, pursuant to Section 7(g) of GSD Rule 4 and MBSD Rule 4, if notification is provided to a member that an allocation has been made against the member pursuant to GSD Rule 4 or MBSD Rule 4, as applicable, and that application of the member's Required Fund Deposit is not sufficient to satisfy such obligation to make payment to FICC, the member is required to deliver to FICC by the Close of Business on the next Business Day, or by the Close of Business on the Business Day of issuance of the notification if so determined by FICC, that amount which is necessary to eliminate any such deficiency, unless the member elects to terminate its membership in FICC. To increase transparency of the timeframe under which FICC would require funds from members to satisfy their loss allocation obligations, FICC is proposing that members would receive two (2) Business Days' notice of a loss allocation, and members would be required to pay the requisite amount no later than the second Business Day following issuance of such notice. 22 Members would have five (5) Business Days ²³ from the issuance of the first Loss Allocation Notice in any round of an Event Period to decide whether to withdraw from membership.

Each round would allow a Tier One Netting Member or Tier One Member, as applicable, the opportunity to notify FICC of its election to withdraw from membership after satisfaction of the losses allocated in such round. Multiple Loss Allocation Notices may be issued with respect to each round to allocate losses up to the round cap.

Specifically, the first round and each subsequent round of loss allocation would allocate losses up to a round cap of the aggregate of all Loss Allocation Caps of those Tier One Netting Members or Tier One Members, as applicable, included in the round. If a Tier One Netting Member or Tier One Member, as

applicable, provides notice of its election to withdraw from membership, it would be subject to loss allocation in that round, up to its Loss Allocation Cap. If the first round of loss allocation does not fully cover FICC's losses, a second round will be noticed to those members that did not elect to withdraw from membership in the previous round; however, as noted above, the amount of any second or subsequent round cap may differ from the first or preceding round cap because there may be fewer Tier One Netting Members or Tier One Members, as applicable, in a second or subsequent round if Tier One Netting Members or Tier One Members, as applicable, elect to withdraw from membership with GSD or MBSD, as applicable, as provided in proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, following the first Loss Allocation Notice in any round.

Pursuant to the proposed rule change, in order to avail itself of its Loss Allocation Cap, a Tier One Netting Member or Tier One Member, as applicable, would need to follow the requirements in proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, which would provide that the Tier One Netting Member or Tier One Member, as applicable, must: (i) Specify in its Loss Allocation Withdrawal Notice an effective date of withdrawal, which date shall not be prior to the scheduled final settlement date of any remaining obligations owed by the member to FICC, unless otherwise approved by FICC, and (ii) as of the time of such member's submission of the Loss Allocation Withdrawal Notice, cease submitting transactions to FICC for processing, clearance or settlement, unless otherwise approved by FICC.

As proposed, a Tier One Netting Member or a Tier One Member, as applicable, that withdraws in compliance with proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, would remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under GSD Rule 4 or MBSD Rule 4, as applicable; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap (as fixed in the round for which it withdrew).

The proposed rule changes are designed to enable FICC to continue the loss allocation process in successive rounds until all of FICC's losses are allocated. To the extent that the Loss Allocation Cap of a Tier One Netting Member or Tier One Member, as applicable, exceeds such member's

²⁰ Current Section 13 of GSD Rule 3 and MBSD Rule 3 requires a member to provide FICC with 10 days written notice of the member's termination; however, FICC, in its discretion, may accept such termination within a shorter notice period. Supra note 5

²¹ If a member's Loss Allocation Cap exceeds the member's then-current Required Fund Deposit, it must still cover the excess amount.

²² FICC believes that allowing members two (2) Business Days to satisfy their loss allocation obligations would provide Members sufficient notice to arrange funding, if necessary, while allowing FICC to address losses in a timely manner.

²³ Supra note 19.

Required Fund Deposit on the first day of an Event Period, FICC may in its discretion retain any excess amounts on deposit from the member, up to the Loss Allocation Cap of a Tier One Netting Member or Tier One Member, as applicable.

The proposed rule changes relating to capping withdrawing members' loss allocation exposure and related changes to the withdrawal process are set forth in proposed Sections 7 and 7b of GSD Rule 4 and Sections 7 and 7b of MBSD Rule 4, as further described below.

B. Changes To Align Loss Allocation Rules

The proposed rule changes would align the loss allocation rules, to the extent practicable and appropriate, of the three DTCC Clearing Agencies so as to provide consistent treatment, especially for firms that are participants of two or more DTCC Clearing Agencies. As proposed, the loss allocation waterfall and certain related provisions, e.g., returning a former member's Clearing Fund, would be consistent across the DTCC Clearing Agencies to the extent practicable and appropriate. The proposed rule changes of FICC that would align loss allocation rules of the DTCC Clearing Agencies are set forth in proposed Sections 1, 5, 6, 10, and 11 of GSD Rule 4 and MBSD Rule 4, as further described below.

C. Clarifying Changes Relating to Loss Allocation

The proposed rule changes are intended to make the provisions in the Rules governing loss allocation more transparent and accessible to members. In particular, FICC is proposing the following changes relating to loss allocation to clarify members' obligations for Declared Non-Default Loss Events.

Aside from losses that FICC might face as a result of a Defaulting Member Event, FICC could incur non-default losses incident to each Division's clearance and settlement business. ²⁴ The GSD Rules and the MBSD Rules currently permit FICC to apply Clearing Fund to non-default losses. ²⁵ Section 5 of GSD Rule 4 and MBSD Rule 4 provides that the use of Clearing Fund deposits is limited to satisfaction of

losses or liabilities of FICC, which includes losses or liabilities that are otherwise incident to the operation of the clearance and settlement business of FICC, although the application of Clearing Fund to such losses or liabilities is more limited under MBSD Rule 4 when compared to GSD Rule 4.26 Section 7(f) of GSD Rule 4 and MBSD Rule 4 provides that any loss or liability incurred by the Corporation incident to its clearance and settlement business arising other than from a Remaining Loss shall be allocated among Tier One Netting Members or Tier One Members, as applicable, ratably, in accordance with their Average Required Clearing Fund Deposits.27

If there is a failure of FICC following a non-default loss, such occurrence would affect members in much the same way as a failure of FICC following a Defaulting Member Event. Accordingly, FICC is proposing rule changes to enhance the provisions relating to non-default losses by clarifying members' obligations for such losses and aligning the non-default loss provisions in the GSD Rules and the MBSD Rules.

Specifically, for both the GSD Rules and the MBSD Rules, FICC is proposing enhancement of the governance around non-default losses that would trigger loss allocation to Tier One Netting Members or Tier One Members, as applicable, by specifying that the Board of Directors would have to determine that there is a non-default loss that may be a significant and substantial loss or liability that may materially impair the ability of FICC to provide clearance and

settlement services in an orderly manner and will potentially generate losses to be mutualized among the Tier One Netting Members or Tier One Members, as applicable, in order to ensure that FICC may continue to offer clearance and settlement services in an orderly manner. The proposed rule change would provide that FICC would then be required to promptly notify members of this determination (a "Declared Non-Default Loss Event"). In addition, FICC is proposing to better align the interest of FICC with those of its members by stipulating a mandatory Corporate Contribution apply to a Declared Non-Default Loss Event prior to any allocation of the loss among members, as described above. Additionally, FICC is proposing language to clarify members' obligations for Declared Non-Default Loss Events.

Under the proposal, FICC would clarify the Rules of both Divisions to make clear that Tier One Netting Members or Tier One Members, as applicable, are subject to loss allocation for non-default losses (*i.e.*, Declared Non-Default Loss Events under the proposal) and Tier Two Members are not subject to loss allocation for non-default losses.

The proposed rule changes relating to Declared Non-Default Loss Events and members' obligations for such events are set forth in proposed Section 7 of GSD Rule 4 and Section 7 of MBSD Rule 4, as further described below.

D. Amending Language Regarding FICC's Use of MBSD Clearing Fund

The proposed rule change would delete language currently in Section 5 of MBSD Rule 4 that limits certain uses by FICC of the MBSD Clearing Fund to "unexpected or unusual" requirements for funds that represent a "small percentage" of the MBSD Clearing Fund. FICC believes that these limiting phrases (which appear in connection with FICC's use of MBSD Clearing Fund to cover losses and liabilities incident to its clearance and settlement business outside the context of an MBSD Defaulting Member Event as well as to cover certain liquidity needs) are vague and imprecise, and should be replaced in their entirety. Specifically, FICC is proposing to delete the limiting language with respect to FICC's use of MBSD Clearing Fund to cover losses and liabilities incident to its clearance and settlement business outside the context of an MBSD Defaulting Member Event so as to not have such language be interpreted as impairing FICC's ability to access the MBSD Clearing Fund in order to manage non-default losses. FICC is also proposing to delete

²⁴ Non-default losses may arise from events such as damage to physical assets, a cyber-attack, or custody and investment losses.

²⁵ Arguably there is an ambiguity created by the first paragraph of Section 7 in both GSD Rule 4 and MBSD Rule 4, which suggests that losses or liabilities may only be allocated in a member default scenario, while Section 5 in both GSD Rule 4 and MBSD Rule 4 makes it clear that the applicable Division's Clearing Fund may be used to satisfy non-default losses.

²⁶ Section 5 of GSD Rule 4 provides that "The use of the Clearing Fund deposits shall be limited to satisfaction of losses or liabilities of the Corporation . . . otherwise incident to the clearance and settlement business of the Corporation . . ." *Supra* note 5.

Section 5 of MBSD Rule 4 provides that "The use of the Clearing Fund deposits and assets and property on which the Corporation has a lien on shall be limited to satisfaction of losses or liabilities of the Corporation . . . otherwise incident to the clearance and settlement business of the Corporation with respect to losses and liabilities to meet unexpected or unusual requirements for funds that represent a small percentage of the Clearing Fund. . ." Supra note 5.

²⁷ Section 7(f) of GSD Rule 4 provides that "Any loss or liability incurred by the Corporation incident to its clearance and settlement business . . . arising other than from a Remaining Loss (hereinafter, an "Other Loss") shall be allocated among Tier One Netting Members, ratably, in accordance with the respective amounts of their Average Required FICC Clearing Fund Deposits. Supra note 5.

Section 7(f) of MBSD Rule 4 provides that "Any loss or liability incurred by the Corporation incident to its clearance and settlement business . . . arising other than from a Remaining Loss (hereinafter, an "Other Loss"), shall be allocated among Tier One Members, ratably, in accordance with the respective amounts of their Average Required Clearing Fund Deposits. Supra note 5.

the limiting language with respect to FICC's use of MBSD Clearing Fund to cover certain liquidity needs because the effect of the limitation in this context is confusing and unclear.

The proposed rule changes relating to FICC's use of MBSD Clearing Fund are set forth in proposed Section 5 of MBSD Rule 4, as further described below.

The foregoing changes as well as other changes (including a number of conforming and technical changes) that FICC is proposing in order to improve the transparency and accessibility of the Rules are described in detail below.

E. Loss Allocation Waterfall Comparison

The following example ²⁸ illustrates the differences between the current and proposed loss allocation provisions:

Assumptions

(i) Firms A, B, and X are each a GSD Netting Member and an MBSD Clearing Member and are referred to as Member A, Member B, and Member X,

respectively.

(ii) Member A defaults on a Business Day (Day 1). On the same day, FICC ceases to act for Member A and notifies members of the cease to act. After liquidating Member A's portfolio and applying Member A's Clearing Fund deposit, FICC has a total loss of \$350 million, with \$200 million in GSD and \$150 million in MBSD.

(iii) Member X voluntarily retires from membership five (5) Business Days after FICC ceases to act for Member A

(Day 6).

(iv) Member B defaults seven (7) Business Days after FICC ceases to act for Member A (Day 8). On the same day, FICC ceases to act for Member B and notifies members of the cease to act. After liquidating Member B's portfolio and applying Member B's Clearing Fund deposit, FICC has a total loss of \$350 million, with \$200 million in GSD and \$150 million in MBSD.

(v) The current FICC loss provisions require FICC to contribute up to 25% of its retained earnings as a corporate contribution. For the purposes of this example, it is assumed that FICC will contribute 25% of its retained earnings. The amount of FICC's retained earnings is \$176 million.

(vi) FICC's General Business Risk Capital Requirement is \$98 million.

Current Loss Allocation

Under the current loss allocation provisions, with respect to the losses arising out of Member A's default, FICC will contribute a total of \$44 million (\$176 million * 25%) from retained earnings, 29 with approximately \$25 million (\$44 million* (\$200 million/\$350 million)) for GSD and approximately \$19 million (\$44 million* (\$150 million/\$350 million)) for MBSD. FICC will then allocate the remaining GSD loss of \$175 million (\$200 million - \$25 million) to GSD Tier One Netting Members and the remaining MBSD loss of \$131 million (\$150 million - \$19 million) to MBSD Tier One Members.

With respect to losses arising out of Member B's default, FICC will contribute a total of approximately \$33 million ((\$176 million - \$44 million) *25%) from retained earnings, with approximately \$19 million (\$33 million (\$200 million/\$350 million)) for GSD and approximately \$14 million (\$33 million * (\$150 million/\$350 million)) for MBSD. FICC will then allocate the remaining GSD loss of \$181 million (\$200 million - \$19 million) to GSDTier One Netting Members and the remaining MBSD loss of \$136 million (\$150 million - \$14 million) to MBSD Tier One Members.

Altogether, with respect to losses arising out of defaults of Member A and Member B, FICC will contribute a total of approximately \$77 million of retained earnings, with approximately \$44 million for GSD and approximately \$33 million for MBSD. FICC will allocate losses of \$356 million to GSD Tier One Netting Members and \$267 million to MBSD Tier One Members.

Proposed Loss Allocation

Under the proposed loss allocation provisions, a Defaulting Member Event with respect to Member A's default would have occurred on Day One, and a Defaulting Member Event with respect to Member B's default would have occurred on Day 8. Because the Defaulting Member Events occurred during a 10-business day period, they would be grouped together into an Event Period for purposes of allocating losses to members. The Event Period would begin on the 1st business day and end on the 10th business day.

With respect to losses arising out of Member A's default, FICC would apply a Corporate Contribution of \$49 million (\$98 million * 50%),³⁰ with

approximately \$32 million (\$49 million (\$10 billion/\$15.2 billion)) for GSD and approximately \$17 million (\$49 million * (\$5.2 billion/\$15.2 billion)) for MBSD. FICC would then allocate the remaining GSD loss of \$168 million (\$200 million - \$32 million) to GSDTier One Netting Members and the remaining MBSD loss of \$133 million (\$150 million - \$17 million) to MBSDTier One Members. With respect to losses arising out of Member B's default, FICC would not apply a Corporate Contribution since it would have already contributed the maximum Corporate Contribution of 50% of its General Business Risk Capital Requirement. With respect to losses arising out of Member B's default, FICC would allocate the GSD loss of \$200 million to GSD Tier One Netting Members and the MBSD loss of \$150 million to MBSD Tier One Members. Because Member X was a member in both Divisions on the first day of the Event Period, Member X would be subject to loss allocation with respect to all events occurring during the Event Period, even if the event occurred after its retirement. Therefore, Member X would be subject to loss allocation with respect to Member B's default.

Altogether, with respect to losses arising out of defaults of Member A and Member B, FICC would apply a Corporate Contribution of \$49 million, with approximately \$32 million for GSD and approximately \$17 million for MBSD. FICC would allocate losses of \$368 million to GSD Tier One Netting Members and \$283 million to MBSD Tier One Members.

The principal differences in the above example are due to (i) the proposed changes to the calculation and application of the Corporate Contribution and (ii) the proposed introduction of an Event Period.

(ii) Detailed Description of the Proposed Rule Changes Related to Loss Allocation

A. Proposed Changes to GSD Rule 4 (Clearing Fund and Loss Allocation) and MBSD Rule 4 (Clearing Fund and Loss Allocation)

Overview of GSD Rule 4 and MBSD Rule 4

GSD Rule 4 and MBSD Rule 4 currently address Clearing Fund requirements and loss allocation obligations, as well as permissible uses of the Clearing Fund. These Rules address the various Clearing Fund calculations for each Division's Clearing

²⁸ For purposes of this example, FICC has assumed that no losses have arisen that apply to Tier Two Netting Members, Tier Two Members, or CCIT Members.

²⁹ The retained earnings are applied to the respective Divisions in the same proportion that the losses of that Division bear to the total losses of both Divisions.

³⁰ The Corporate Contribution would be applied to the respective Divisions in the same proportion that the aggregate Average RFDs of all members in that Division bear to the aggregate Average RFDs of all members in both Divisions. For the purposes of

this example, FICC has assumed that the aggregate Average RFDs of all GSD members is \$10 billion and the aggregate Average RFDs of all MBSD members is \$5.2 billion.

Fund and set forth rights, obligations and other aspects associated with each Division's Clearing Fund, as well as each Division's loss allocation process. GSD Rule 4 and MBSD Rule 4 are each currently organized into 12 sections. Sections of these Rules that FICC is proposing to change are described below.

Section 1 of GSD Rule 4 and MBSD Rule 4

Currently, Section 1 of GSD Rule 4 and MBSD Rule 4 set forth the requirement that each GSD Netting Member and each MBSD Clearing Member make and maintain a deposit to the Clearing Fund at the minimum level set forth in the respective Rule 4 and note that the timing of such payment is set forth in another section of the respective Rule 4. Current Section 1 of the respective rule also provides that the deposits to the Clearing Fund will be held by FICC or its designated agents. Current Section 1 of MBSD Rule 4 also defines the term "Transaction" for purposes of MBSD Rule 4 and references a Member's obligation to replenish the deficit in its Required Fund Deposit if it is charged by FICC under certain circumstances.

FICC is proposing to rename the subheading of Section 1 of Rule 4 in both the GSD Rules and MBSD Rules from "General" to "Required Fund Deposits" and to restructure the wording of the provisions for clarity and readability.

Under the proposed rule change, Section 1 of GSD Rule 4 and Section 1 of MBSD Rule 4 would continue to have the same provisions as they relate to Netting Members or Clearing Members, as applicable, except for the following: (i) The language throughout the sections would be reorganized, streamlined and clarified, and (ii) language would be added regarding additional deposits maintained by the Netting Members or Clearing Members, as applicable, at FICC, and highlight for members that such additional deposits would be deemed to be part of the Clearing Fund and the member's Actual Deposit (as discussed below and as defined in the proposed rule change) but would not be deemed to be part of the member's Required Fund Deposit.

The proposed language regarding maintenance of a member's Actual Deposit would also make it clear that FICC will not be required to segregate such deposit, but shall maintain books and records concerning the assets that constitute each member's Actual Deposit.

In addition, FICC proposes a technical change to update a cross reference in

Section 1 of GSD Rule 4 and MBSD Rule 4.

Furthermore, in Section 1 of MBSD Rule 4, FICC is proposing to move the definition of "Transactions" to proposed Section 2(a) of MBSD Rule 4, where the first usage of "Transactions" in MBSD Rule 4 appears. FICC is also proposing to delete the last sentence in Section 1 of MBSD Rule 4, which references a Member's obligation to replenish the deficit in its Required Fund Deposit if it is charged by FICC under certain circumstances, because it would no longer be relevant under the proposed rule change to Section 7 of MBSD Rule 4, as FICC would require members to pay their loss allocation amounts instead of charging their Required Fund Deposits for Clearing Fund losses.

Section 2 of GSD Rule 4 and MBSD Rule 4

Current Section 2 of GSD Rule 4 and MBSD Rule 4 set forth more detailed requirements pertaining to members' Required Fund Deposits. FICC is proposing to rename the subheadings in these sections from "Required Fund Deposit" to "Required Fund Deposit Requirements" in order to better reflect the purpose of this section.

In addition, FICC is proposing to expand the definition of "Legal Risk" in both the GSD and MBSD provisions (current Section 2(e) of GSD Rule 4 and Section 2(f) of MBSD Rule 4) by revising the parameters of Legal Risk so that it would not be limited to laws applicable to a member's insolvency or bankruptcy, as FICC believes that Legal Risk may arise outside the context of an insolvency or bankruptcy event regarding a member, and FICC should be permitted to adequately protect itself in those non- insolvency/bankruptcy circumstances as well.

For better organization of Rule 4, FICC is also proposing to relocate the provision on minimum Clearing Fund cash requirements (current Section 2(b) of GSD Rule 4 and Section 2(d) of MBSD Rule 4) to the section in each of GSD Rule 4 and MBSD Rule 4 dealing specifically with the form of Clearing Fund deposits (proposed Section 3 of GSD Rule 4 and MBSD Rule 4). This would necessitate the re-lettering of the provisions in Section 2. In addition, as stated above, the provision regarding the definition of "Transactions" for purposes of MBSD Rule 4 would be moved to proposed Section 2(a) from current Section 1.

FICC is proposing technical changes to correct typographical errors in current Section 2 of GSD Rule 4. Sections 3, 3a and 3b of GSD Rule 4 and MBSD Rule 4

Currently, Sections 3, 3a and 3b of GSD Rule 4 and MBSD Rule 4 address the permissible form of Clearing Fund deposits and contain detailed requirements regarding each form. FICC is proposing changes to improve the readability of these sections.

In addition, for better organization of the subject matter, FICC is proposing to move certain paragraphs from one section to another, including (i) moving clauses (b) and (d) in current Section 2 of GSD Rule 4 and MBSD Rule 4, respectively, to proposed Section 3 of GSD Rule 4 and MBSD Rule 4 and (ii) moving the last paragraph of current Section 3 in GSD Rule 4 and MBSD Rule 4 to proposed Section 3b of GSD Rule 4 and MBSD Rule 4.

Under the proposed rule change, FICC is also proposing to update the cash investment provision in Section 3a of GSD Rule 4 and MBSD Rule 4 to reflect the Clearing Agency Investment Policy adopted by FICC 31 and to define Clearing Fund Cash as (i) cash deposited by a Netting Member or Clearing Member, as applicable, as part of its Actual Deposit, (ii) the proceeds of (x) any loans made to FICC secured by the pledge by FICC of Eligible Clearing Fund Securities pledged to FICC or (y) any sales of Eligible Clearing Fund Securities pledged to FICC, (iii) cash receipts from any investment of, repurchase or reverse repurchase agreements relating to, or liquidation of, Clearing Fund assets, and (iv) cash payments on Eligible Letters of Credit. Lastly, FICC is proposing technical changes to correct typographical errors in current Section 3 of MBSD Rule 4 and current Section 3b of GSD Rule 4.

³¹ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-FICC-2016-005). The Clearing Agency Investment Policy (the "Policy") governs the management, custody, and investment of cash deposited to the GSD and MBSD Clearing Funds, the proprietary liquid net assets (cash and cash equivalents) of FICC and other funds held by FICC. The Policy sets forth guiding principles for the investment of those funds, which include adherence to a conservative investment philosophy that places the highest priority on maximizing liquidity and avoiding risk, as well as mandating the segregation and separation of funds. The Policy also addresses the process for evaluating credit ratings of counterparties and identifies permitted investments within specified parameters. In general, assets are required to be held by regulated and creditworthy financial institution counterparties and invested in financial instruments that, with respect to the GSD and MBSD Clearing Funds, may include deposits with banks, including the Federal Reserve Bank of New York, collateralized reverse-repurchase agreements, direct obligations of the U.S. government and money-market mutual funds.

Section 4 of GSD Rule 4 and MBSD Rule 4

Currently, Section 4 of GSD Rule 4 and MBSD Rule 4 address the granting of a first priority perfected security interest by each Netting Member or Clearing Member, as applicable, in all assets and property placed by the member in the possession of FICC (or its agents acting on its behalf). FICC is not proposing any substantive changes to these sections except for streamlining the provisions for readability and clarity, and adding "Actual Deposit" as a defined term to refer to Eligible Clearing Fund Securities, funds and assets pledged to FICC to secure any and all obligations and liabilities of a Netting Member or a Clearing Member, as applicable, to FICC.

Section 5 of GSD Rule 4 and MBSD Rule 4

Currently, Section 5 of GSD Rule 4 and MBSD Rule 4 describe the use of each Division's Clearing Fund. FICC is proposing to rename the subheading of this section from "Use of Deposits and Payments" to "Use of Clearing Fund" to better reflect the purpose of the section.

Under the proposed rule change, FICC is also proposing changes to streamline this section for clarity and readability and to align the GSD Rules and MBSD Rules. Specifically, FICC is proposing to delete the first paragraph of current Section 5 of GSD Rule 4 and MBSD Rule 4 and replace it with clearer language that sets forth the permitted uses of each Division's Clearing Fund. Specifically, the proposed Section 5 of GSD Rule 4 and MBSD Rule 4 provides that each Division's Clearing Fund would only be used by FICC (i) to secure each member's performance of obligations to FICC, including, without limitation, each member's obligations with respect to any loss allocations as set forth in proposed Section 7 of GSD Rule 4 and MBSD Rule 4 and any obligations arising from a Cross-Guaranty Agreement pursuant to GSD Rule 41 or MBSD Rule 32, as applicable, or a Cross-Margining Agreement pursuant to GSD Rule 43, (ii) to provide liquidity to FICC to meet its settlement obligations, including, without limitation, through the direct use of cash in the GSD Clearing Fund or MBSD Clearing Fund, as applicable, or through the pledge or rehypothecation of pledged Eligible Clearing Fund Securities in order to secure liquidity, and (iii) for investment as set forth in proposed Section 3a of GSD Rule 4 and MBSD Rule 4.

The current first paragraph of Section 5 of GSD Rule 4 and MBSD Rule 4 provides that if FICC pledges,

hypothecates, encumbers, borrows, or applies any part of the respective Division's Clearing Fund deposits to satisfy any liability, obligation, or liquidity requirements for more than thirty (30) days, FICC, at the Close of Business on the 30th day (or on the first Business Day thereafter) will consider the amount used as an actual loss to the respective Division's Clearing Fund and immediately allocate such loss in accordance with Section 7 of GSD Rule 4 or MBSD Rule 4, as applicable. As proposed, FICC would retain this provision conceptually but replace it with clearer and streamlined language that provides that each time FICC uses any part of the respective Division's Clearing Fund for more than 30 calendar days to provide liquidity to FICC to meet its settlement obligations, including, without limitation, through the direct use of cash in the Clearing Fund or through the pledge or rehypothecation of pledged Eligible Clearing Fund Securities in order to secure liquidity, FICC, at the Close of Business on the 30th calendar day (or on the first Business Day thereafter) from the day of such use, would consider the amount used but not yet repaid as a loss to the Clearing Fund incurred as a result of a Defaulting Member Event and immediately allocate such loss in accordance with proposed Section 7 of GSD Rule 4 or MBSD Rule 4, as applicable.

The proposed rule change also includes deleting language currently in Section 5 of MBSD Rule 4 that limits certain uses by FICC of the MBSD Clearing Fund to "unexpected or unusual" requirements for funds that represent a "small percentage" of the MBSD Clearing Fund. FICC believes that these limiting phrases (which appear in connection with FICC's use of MBSD Clearing Fund to cover losses and liabilities incident to its clearance and settlement business outside the context of an MBSD Defaulting Member Event as well as to cover certain liquidity needs) are vague and imprecise, and should be replaced in their entirety. Specifically, FICC is proposing to delete the limiting language with respect to FICC's use of MBSD Clearing Fund to cover losses and liabilities incident to its clearance and settlement business outside of an MBSD Defaulting Member Event so as to not have such language be interpreted as impairing FICC's ability to access the MBSD Clearing Fund in order to manage non-default losses. FICC is also proposing to delete the limiting language with respect to FICC's use of MBSD Clearing Fund to cover certain liquidity needs because

the effect of the limitation in this context is confusing and unclear.

In addition, FICC is proposing to delete the last paragraph in current Section 5 of GSD Rule 4 and MBSD Rule 4 because these paragraphs address the application of a member's deposits to the applicable Clearing Fund to cover the allocation of a loss or liability incurred by FICC. These paragraphs would no longer be relevant, because, under the proposed Section 7 of GSD Rule 4 and MBSD Rule 4 (discussed below), FICC would not apply the member's deposit to the Clearing Fund unless the member does not satisfy payment of its allocated loss amount within the required timeframe. These paragraphs also currently include provisions regarding other agreements, such as a Cross-Guaranty Agreement, that pertain to a Defaulting Member, and such provisions would now be covered by proposed Section 6 of GSD Rule 4 and MBSD Rule 4.

Section 6 of GSD Rule 4 and MBSD Rule 4

Currently, Section 6 of GSD Rule 4 and MBSD Rule 4 are reserved for future use. FICC is proposing to use this section for provisions relating to the application of deposits to the respective Division's Clearing Fund and other amounts held by FICC to a Defaulting Member's obligations.

FICC is proposing to add a subheading of "Application of Clearing Fund Deposits and Other Amounts to Defaulting Members' Obligations" to Section 6 of GSD Rule 4 and MBSD Rule 4. Under the proposed rule change, for better organization by subject matter, FICC is also proposing to relocate certain provisions to these sections from the respective current Section 7 of GSD Rule 4 and MBSD Rule 4, which addresses FICC's application of Clearing Fund deposits and other assets held by FICC securing a Defaulting Member's obligations to FICC.

For additional clarity and for consistency with the loss allocation rules of the other DTCC Clearing Agencies, FICC proposes to add a provision which makes it clear that, if FICC applies a Defaulting Member's Clearing Fund deposits, FICC may take any and all actions with respect to the Defaulting Member's Actual Deposits, including assignment, transfer, and sale of any Eligible Clearing Fund Securities, that FICC determines is appropriate.

Sections 7, 7a and 7b of GSD Rule 4 and MBSD Rule 4

Current Section 7 of GSD Rule 4 and MBSD Rule 4 contains FICC's current loss allocation waterfall for losses or liabilities incurred by FICC. With respect to any loss or liability incurred by FICC as the result of the failure of a Defaulting Member to fulfill its obligations to FICC, the loss allocation waterfall for each Division currently provides:

(i) Application of any Clearing Fund deposits and other collateral held by FICC securing a Defaulting Member's obligations to FICC and additional resources as are applicable to the

Defaulting Member.

(ii) If a loss or liability remains after the application of the Defaulting Member's collateral and resources, FICC would apply up to 25% of FICC's existing retained earnings, or such higher amount as the Board of Directors determines.

(iii) If a loss or liability still remains after the application of the retained earnings, FICC would apply the loss or liability to members as follows:

(a) If the remaining loss or liability is attributable to Tier One Netting Members or Tier One Members, as applicable, then FICC will allocate such loss or liability to Tier One Netting Members or Tier One Members, as applicable, by assessing the Required Fund Deposit maintained by each such member an amount up to \$50,000, in an equal basis per Tier One Netting Member or Tier One Member, as applicable.

(b) If the remaining loss or liability is attributable to Tier Two Members, then FICC will allocate such loss or liability to Tier Two Members based upon their trading activity with the Defaulting Member that resulted in a loss.

(iv) If there is any loss or liability that still remains after the application of (ii) and (iii) above that is attributable to Tier One Netting Members or Tier One Members, as applicable, then FICC will allocate such loss or liability among Tier One Netting Members or Tier One Members, as applicable, ratably based on the amount of each Tier One Netting Member's or Tier One Member's Required Fund Deposit and based on the average daily level of such deposit over the prior twelve (12) months (or such shorter period as may be available if the member has not maintained a deposit over such time period).

Current Section 7(f) of GSD Rule 4 and MBSD Rule 4 also provides that Other Losses shall be allocated among Tier One Netting Members or Tier One Members, as applicable, ratably in accordance with the respective amounts of each Tier One Netting Member's or Tier One Member's Required Fund Deposit and based on the average daily level of such deposit over the prior twelve (12) months (or such shorter

period as may be available if the member has not maintained a deposit over such time period).

Currently, pursuant to Section 7(e) of GSD Rule 4, an Inter-Dealer Broker Netting Member, or a Non-IDB Repo Broker with respect to activity in its Segregated Broker Account, will not be subject to an aggregate allocation loss for any single loss-allocation event that exceeds \$5 million. FICC believes that it is appropriate for GSD to retain this cap under the proposed rule change because the Inter-Dealer Broker Netting Members are required to limit their business as provided in Section 8(e) of GSD Rule 3, which would in turn minimize the potential losses or liabilities that could be incurred by FICC from Inter-Dealer Broker Netting Members. 32 FICC believes that it is also appropriate for GSD to retain this cap under the proposed rule change for Non-IDB Repo Brokers because their activity in their respective Segregated Broker Accounts would be subject to similar limitations as the Inter-Dealer Broker Netting Members. However, the proposal would apply the cap to an Event Period instead of a single loss event in order to conform with the concept of the Event Period under the proposal. FICC believes applying the cap to an Event Period would continue to reasonably represent the risk profiles of the Inter-Dealer Broker Netting Members, and Non-IDB Repo Brokers with respect to their Segregated Broker Accounts, because they submit affirmed trades from their systems to GSD, with each trade already matched to the counterparty that will ultimately deliver or receive the securities. Therefore, Inter-Dealer Broker Netting Members, and Non-IDB Repo Brokers with respect to their Segregated Broker Accounts, do not generally maintain positions with FICC and present minimal risk to FICC. FICC is also proposing technical changes to replace (i) the term 'Segregated Broker Account' with "Segregated Repo Account" and (ii) the term "Non-IDB Broker" with "Non-IDB Repo Broker," both of which are the correct terms defined in GSD Rule 1.

Current Section 7(g) of GSD Rule 4 and MBSD Rule 4 further provides that if the Required Fund Deposit of the

member being allocated the loss is not sufficient to satisfy its loss allocation obligation, the member is required to deliver to FICC an amount that is necessary to eliminate the deficiency by the Close of Business on the next Business Day, or by the Close of Business on the Business Day of issuance of the notification if so determined by FICC. Under the current Rules, a member may elect to terminate its membership, which would limit its loss allocation to the amount of its Required Fund Deposit for the Business Day on which the notification of such loss allocation is provided to the member. If the member does not elect to terminate its membership and fails to satisfy its Required Fund Deposit within the timeframe specified in the Rules, FICC will cease to act generally with regard to such member pursuant to GSD Rules 21 and 22A or MBSD Rules 14 and 17, as applicable, and may take disciplinary action against such member pursuant to GSD Rule 48 or MBSD Rule 38, as applicable.

Current Section 7(h) of GSD Rule 4 and MBSD Rule 4 requires FICC to promptly notify members and the Commission of the amount involved and the causes if a Remaining Loss or Other Loss occurs. In addition, current Section 7(i) of GSD Rule 4 and MBSD Rule 4 also provides that any increase in Clearing Fund deposit as required by subsection (f) of current Section 2 of GSD Rule 4 or provisions of MBSD Rule 4 regarding special charges or other premiums will not be taken into account when calculating loss allocation based on a GSD Member's Average Required FICC Clearing Fund Deposit amount or an MBSD Member's Average Required

under current Section 7 of GSD Rule 4 and MBSD Rule 4.

Under the proposed rule change, FICC is proposing to rename the subheading of Section 7 of GSD Rule 4 and MBSD Rule 4 to "Loss Allocation Waterfall, Off-the-Market Transactions." In addition, FICC is proposing to restructure its loss allocation waterfall as described below.

Fund Deposit amount, as applicable,

For better organization of the subject matter, FICC is proposing to move certain paragraphs from one section to another, including (i) relocating the last sentence of current Section 7(h) of GSD Rule 4 and MBSD Rule 4 regarding recovery of allocated losses or liabilities by FICC to the fifth paragraph of proposed Section 7 of GSD Rule 4 and MBSD Rule 4, (ii) relocating from current Section 7(a) of GSD Rule 4 and MBSD Rule 4 provisions which address FICC's application of Clearing Fund deposits and other assets held by FICC

³² Pursuant to Section 8(e) of GSD Rule 3, an Inter-Dealer Broker Netting Member is required to (A) limit its business to acting exclusively as a broker, (B) conduct all of its business in Repo Transactions with Netting Members, and (C) conduct at least 90 percent of its business in transactions that are not Repo Transactions with Netting Members. If an Inter-Dealer Broker Netting Member fails to comply with these requirements, then the Inter-Dealer Broker Netting Member shall be considered by FICC as a Dealer Netting Member. Supra note 5.

securing a Defaulting Member's obligations to FICC to proposed Section 6 of GSD Rule 4 and MBSD Rule 4, (iii) relocating from current Section 7 of GSD Rule 4 to proposed Section 6 of GSD Rule 4 the provision regarding FICC's right to treat certain payments to an FCO under a Cross-Margining Guaranty as a loss to be allocated, (iv) relocating the provisions in current Section 7(i) of GSD Rule 4 and MBSD Rule 4 regarding certain increases in Clearing Fund deposits not being taken into account when calculating loss allocation so that such provisions would come right after the loss allocation calculation provision, with an updated reference to proposed renumbered Sections 2(d) and 2(e) in GSD Rule 4 and MBSD Rule 4, respectively, and (v) relocating the provision regarding withdrawing members reapplying to become members 33 in the second paragraph of current Section 7(g) of GSD Rule 4 and MBSD Rule 4 to come right after the paragraph regarding the election of a Tier One Netting Member or Tier One Member, as applicable, to withdraw from membership in proposed Section 7 of GSD Rule 4 and MBSD Rule 4.

³³ Current Section 7(g) of GSD Rule 4 provides that a Member that elects to terminate its membership pursuant to alternative (ii) in Section 7(g) of GSD Rule 4 in lieu of being liable to pay an additional assessment amount above its Required Fund Deposit shall not be eligible to re-apply to become a Comparison-Only Member or a Netting Member unless, prior to submitting such application, it makes the payment to FICC provided for in alternative (i) in Section 7(g) of GSD Rule 4, together with interest on that amount at the average of the Federal Funds Rate plus one percent, calculated from the date on which the Remaining Loss or Other Loss was incurred by FICC until the date of such payment. Supra note 5.

Current Section 7(g) of MBSD Rule 4 provides that a Member that elects to terminate its membership pursuant to alternative (ii) in Section 7(g) of MBSD Rule 4 in lieu of being liable to pay an additional assessment amount above its Required Fund Deposit shall not be eligible to reapply to become a Clearing Member unless, prior to submitting such application, it makes the payment to FICC provided for in alternative (i) in Section 7(g) of MBSD Rule 4, together with interest on that amount at the average of the Federal Funds Rate plus one percent, calculated from the date on which the Remaining Loss or Other Loss was incurred by FICC until the date of such payment. Supra note 5.

The condition for re-application was historically in the rules of Government Securities Clearing Corporation ("GSCC") (FICC's predecessor) to solidify GSCC's membership base and thereby discourage members from withdrawing from membership during a time of stress solely to avoid their loss allocation obligations. This condition was later incorporated into the GSD Rules and MBSD Rules. In the interest of continuing to encourage members to remain in FICC central clearing in order to preserve the robustness of the Treasury and mortgage-backed securities markets, FICC would like to retain this condition for re-application in the GSD and MBSD Rules as is. As the provision applies to a remote contingency and, without an immediate business need, NSCC and DTC would prefer not to add this provision at this time.

Furthermore, in order to enhance readability and clarity, FICC is proposing a number of changes to streamline the language in these provisions.

In Section 7 of GSD Rule 4 and MBSD Rule 4, as applicable, FICC is proposing to make it clear that no loss allocation under proposed GSD Rule 4 or proposed MBSD Rule 4, as applicable, would constitute a waiver of any claim FICC may have against a member for any losses or liabilities to which the member is subject under the Rules, including, without limitation, any loss or liability to which it may be subject under proposed GSD Rule 4 or proposed MBSD Rule 4, as applicable. FICC is proposing this change to preserve its legal rights and to make it clear to members that loss allocation under proposed GSD Rule 4 and proposed MBSD Rule 4 would not be deemed as FICC waiving any claims it may have against a member for any losses or liabilities to which the member is subject under the Rules.

Under the proposal, Section 7 of GSD Rule 4 and MBSD Rule 4 would make clear that the loss allocation waterfall applies to losses and liabilities (i) arising out of or relating to a default of a member or (ii) otherwise incident to the clearance and settlement business of FICC (i.e., non-default losses). The loss allocation waterfall would be triggered if FICC incurs a loss or liability arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event.

As proposed, Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that, for the purposes of GSD Rule 4 or MBSD Rule 4, as applicable, the term "Defaulting Member" would mean a GSD Member or MBSD Member, as applicable, for which FICC has ceased to act pursuant to GSD Rule 21 or GSD Rule 22,34 or MBSD Rule 14 or MBSD Rule 16,35 as applicable, the term "Defaulting Member Event" would mean the determination by FICC to cease to act for a GSD Member or MBSD Member, as applicable, pursuant to GSD Rule 21 or GSD Rule 22, or MBSD Rule 14 or MBSD Rule 16, as applicable, and the term "Declared Non-Default Loss Event" would mean the determination by the Board of Directors that a loss or

liability incident to the clearance and settlement business of FICC may be a significant and substantial loss or liability that may materially impair the ability of FICC to provide clearance and settlement services in an orderly manner and will potentially generate losses to be mutualized among members in order to ensure that FICC may continue to offer clearance and settlement services in an orderly manner.

As proposed, each member would be obligated to FICC for the entire amount of any loss or liability incurred by FICC arising out of or relating to any Defaulting Member Event with respect to such member. Under the proposal, to the extent that such loss or liability is not satisfied pursuant to proposed Section 6 of GSD Rule 4 or MBSD Rule 4, as applicable, FICC would apply a Corporate Contribution thereto and charge the remaining amount of such loss or liability ratably to other members, as provided in proposed Section 7 of GSD Rule 4 and MBSD Rule 4.

Under proposed Section 7 of GSD Rule 4 and MBSD Rule 4, the loss allocation waterfall would begin with a corporate contribution from FICC ("Corporate Contribution"), as is the case under the current Rules, but in a different form than under the current Section 7 of GSD Rule 4 and MBSD Rule 4 described above. Today, Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4 provide that, if FICC incurs any loss or liability as the result of the failure of a Defaulting Member to fulfill its obligations to FICC, FICC will contribute up to 25% of its existing retained earnings (or such higher amount as the Board of Directors shall determine), to such loss or liability; however, no corporate contribution from FICC is currently required for losses resulting other than those from Member impairments. Under the proposal, FICC would add a proposed new Section 7a to GSD Rule 4 and MBSD Rule 4 with a subheading of "Corporate Contribution" and define FICC's Corporate Contribution with respect to any loss allocation pursuant to proposed Section 7 of GSD Rule 4 or MBSD Rule 4, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, as an amount that is equal to fifty (50) percent of the amount calculated by FICC in respect of its General Business Risk Capital Requirement as of the end of the calendar quarter immediately preceding the Event Period.36 The proposed rule change would specify

³⁴ FICC may cease to act for a GSD Member pursuant to any of the circumstances set forth under GSD Rule 21 (Restrictions on Access to Services) or GSD Rule 22 (Insolvency of a Member). *Supra* note

³⁵ FICC may cease to act for an MBSD Member pursuant to any of the circumstances set forth under MBSD Rule 14 (Restrictions on Access to Services) or MBSD Rule 16 (Insolvency of a Member). Supra

³⁶ Supra note 9.

that FICC's General Business Risk Capital Requirement, as defined in FICC's Clearing Agency Policy on Capital Requirements, ³⁷ is, at a minimum, equal to the regulatory capital that FICC is required to maintain in compliance with Rule 17Ad–22(e)(15) under the Act. ³⁸

As proposed, if FICC applies the Corporate Contribution to a loss or liability arising out of or relating to one or more Defaulting Member Events or Declared Non-Default Loss Events relating to an Event Period, then for any subsequent Event Periods that occur during the two hundred fifty (250) Business Days thereafter,39 the Corporate Contribution would be reduced to the remaining unused portion of the Corporate Contribution amount that was applied for the first Event Period. Proposed Section 7a of both GSD Rule 4 and MBSD Rule 4 would require FICC to notify members of any such reduction to the Corporate Contribution.

Proposed Section 7a to GSD Rule 4 and MBSD Rule 4 would also make clear that there would be one FICC Corporate Contribution, the amount of which would be available to both Divisions and would be applied against a loss or liability in either Division in the order in which such loss or liability occurs, i.e., FICC would not have two separate Corporate Contributions, one for each Division. As proposed, in the event of a loss or liability relating to an Event Period, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, attributable to only one Division, the Corporate Contribution would be applied to that Division up to the amount then available. Under the proposal, if a loss or liability relating to an Event Period, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, occurs simultaneously at both Divisions, the Corporate Contribution would be applied to the respective Divisions in the same proportion that the aggregate Average RFDs of all members in that Division bears to the aggregate Average RFDs of all members in both Divisions.40

Currently, the Rules do not require FICC to contribute its retained earnings to losses and liabilities other than those from member defaults. Under the proposal, FICC would expand the application of its corporate contribution beyond losses and liabilities as the

result of the failure of a Defaulting Member to fulfill its obligations to FICC. The proposed Corporate Contribution would apply to losses or liabilities relating to or arising out of Defaulting Member Events and Declared Non-Default Loss Events, and would be a mandatory loss contribution by FICC prior to any allocation of the loss among the applicable Division's members.

Current Section 7(b) of GSD Rule 4 and Section 7(c) of MBSD Rule 4 provide FICC the option to contribute amounts higher than the specified percentage of retained earnings as determined by the Board of Directors, to any loss or liability incurred by FICC as the result of the failure of a Defaulting Member to fulfill its obligations to FICC. This option would be retained and expanded under the proposal to also cover non-default losses. Proposed Section 7a of GSD Rule 4 and MBSD Rule 4 would provide that nothing in the Rules would prevent FICC from voluntarily applying amounts greater than the Corporate Contribution against any FICC loss or liability, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation existing at the time.

Proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that FICC shall apply the Corporate Contribution to losses and liabilities that arise out of or relate to one or more Defaulting Member Events and/or (ii) Declared Non-Default Loss Events that occur within an Event Period. The proposed rule change also provides that if losses and liabilities with respect to such Event Period remain unsatisfied following application of the Corporate Contribution, FICC would allocate such losses and liabilities to members, as described below.

As proposed, Section 7 of GSD Rule 4 and MBSD Rule 4 would retain the differentiation in allocating losses to Tier One Netting Members or Tier One Members, as applicable, and Tier Two Members. Specifically, as is the case today, losses or liabilities that arise out of or relate to one or more Defaulting Member Events would be attributable to Tier One Netting Members or Tier One Members, as applicable, and Tier Two Members, while losses or liabilities that arise out of or relate to one or more Declared Non-Default Loss Events would only be attributable to Tier One Netting Members or Tier One Members, as applicable. Tier Two Members would not be subject to loss allocation with respect to Declared Non-Default Loss Events.

Under the proposal, FICC would delete the provision in current Section 7(h) of GSD Rule 4 and MBSD Rule 4 that requires FICC to promptly notify members and the Commission of the amounts involved and the causes if a Remaining Loss or Other Loss occurs because such notification would no longer be necessary under the proposed rule change. Under the proposed rule change, FICC would notify members subject to loss allocation of the amounts being allocated to them in one or more Loss Allocation Notices for both Defaulting Member Events and Declared Non-Default Loss Events. As such, in order to conform to the proposed rule change, FICC is proposing to eliminate the notification to members regarding the amounts involved and the causes if a Remaining Loss or Other Loss occurs that is required under current Section 7(h) of GSD Rule 4 and MBSD Rule 4. FICC is also proposing to delete the notification to the Commission regarding the amounts involved and the causes if a Remaining Loss or Other Loss occurs as required in the same section. While as a practical matter, FICC would notify the Commission of a decision to loss allocate, FICC does not believe such notification needs to be specified in the Rules.

In addition, FICC is proposing to clarify the provision related to Off-the-Market Transactions so that it is clear that loss or liability of FICC in connection with the close-out or liquidation of an Off-the-Market Transaction in the portfolio of a Defaulting Member would be allocated to the Member that was the counterparty to such transaction.

Tier One Netting Members/Tier One Members

For Tier One Netting Members or Tier One Members, as applicable, proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would establish the concept of an "Event Period" to provide for a clear and transparent way of handling multiple loss events occurring in a period of ten (10) Business Days, which would be grouped into an Event Period. ⁴¹ As stated above, both Defaulting Member Events or Declared Non-Default Loss Events could occur within the same Event Period.

Under the proposal, an Event Period with respect to a Defaulting Member Event would begin on the day FICC notifies members that it has ceased to act for the Defaulting Member (or the next Business Day, if such day is not a Business Day). In the case of a Declared Non-Default Loss Event, an Event Period

³⁷ Supra note 10.

³⁸ Supra note 11.

³⁹ Supra note 13.

⁴⁰ Supra note 14.

⁴¹ Supra note 16.

would begin on the day that FICC notifies members of the Declared Non-Default Loss Event (or the next Business Day, if such day is not a Business Day). If a subsequent Defaulting Member Event or Declared Non-Default Loss Event occurs during an Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period.

Proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would also retain the requirement of loss allocation among Tier One Netting Members or Tier One Members, as applicable, if a loss or liability remains after the application of the Corporate Contribution, as described above. In contrast to the current Section 7 where FICC would assess the Required Fund Deposits of Tier One Netting Members or Tier One Members, as applicable, to allocate losses, under the proposal, FICC would require Tier One Netting Members or Tier One Members, as applicable, to pay their loss allocation amounts (leaving their Required Fund Deposits intact).⁴² Loss allocation obligations would continue to be calculated based upon a Tier One Netting Member's or Tier One Member's, as applicable, pro rata share of losses and liabilities (although the pro rata share would be calculated differently than it is today), and Tier One Netting Members or Tier One Members, as applicable, would still retain the ability to voluntarily withdraw from membership and cap their loss allocation obligation (although the loss allocation obligation would also

be calculated differently than it is today).

The proposed rule change to Section 7 of GSD Rule 4 and MBSD Rule 4 would clarify that each Tier One Netting Member or Tier One Member, as applicable, that is a Tier One Netting Member or Tier One Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member) and each Declared Non-Default Loss Event occurring during the Event Period. The proposal would make it clear that any Tier One Netting Member or Tier One Member, as applicable, for which FICC ceases to act on a non-Business Day, triggering an Event Period that commences on the next Business Day, shall be deemed to be a Tier One Netting Member or Tier One Member, as applicable, on the first day of that Event Period.

Ŭnder the proposed rule change, a loss allocation "round" would mean a series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the round cap. When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. FICC may continue the loss allocation process in successive rounds until all losses from the Event Period are allocated among Tier One Netting Members or Tier One Members, as applicable, that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 7b of GSD Rule 4 or MBSD Rule 4.

As proposed, each loss allocation would be communicated to the Tier One Netting Members or Tier One Members, as applicable, by the issuance of a Loss Allocation Notice. Under the proposal, each Tier One Netting Member's or Tier One Member's, as applicable, pro rata share of losses and liabilities to be allocated in any round would be equal to (i) the member's Average RFD divided by (ii) the sum of Average RFD amounts of all members subject to loss allocation in such round.

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Tier One Netting Member or Tier One Member, as

applicable, in that round has five (5) Business Days from the issuance of such first Loss Allocation Notice for the round to notify FICC of its election to withdraw from membership with GSD or MBSD, as applicable, pursuant to proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, and thereby benefit from its Loss Allocation Cap. 43 As proposed, the "Loss Allocation Cap" of a Tier One Netting Member or a Tier One Member, as applicable, would be equal to the greater of (x) its Required Fund Deposit on the first day of the applicable Event Period and (y) its Average RFD.

FICC is proposing to clarify that after a first round of loss allocation with respect to an Event Period, only Tier One Netting Members or Tier One Members, as applicable, that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, would be subject to further loss allocation with respect to that Event Period.

As proposed, each such member's pro rata share of losses and liabilities to be allocated in any round would be equal to (i) the member's Average RFD, divided by (ii) the sum of the Average RFD amounts of all members subject to loss allocation in such round. Each such member would have a maximum payment obligation with respect to any loss allocation round that would be equal to the greater of (x) its Required Fund Deposit on the first day of the applicable Event Period or (y) its Average RFD (such amount would be each member's "Loss Allocation Cap"). Therefore, the sum of the Loss Allocation Caps of the members subject to loss allocation would constitute the maximum amount that FICC would be permitted to allocate in each round. FICC would retain the loss allocation limit of \$5 million for Inter-Dealer Broker Netting Members, or Non-IDB Repo Brokers with respect to activities in their Segregated Broker Accounts, as discussed above.

As proposed, Section 7 of GSD Rule 4 and MBSD Rule 4, would also provide that, to the extent that a Tier One Netting Member's or Tier One Member's, as applicable, Loss Allocation Cap exceeds such member's Required Fund Deposit on the first day of the applicable Event Period, FICC may, in its discretion, retain any excess amounts on deposit from the member, up to the Loss Allocation Cap of the Tier One Netting Member or Tier One Member, as applicable.

⁴² FICC believes that shifting from the two-step methodology of applying the respective Division's Clearing Fund and then requiring members to immediately replenish it to requiring direct payment would increase efficiency, while preserving the right to charge the member's Clearing Fund deposits in the event the member does not timely pay. Such a failure to pay would trigger recourse to the Clearing Fund deposits of the member under proposed Section 6 of GSD Rule 4 or MBSD Rule 4, as applicable. In addition, this change would provide greater stability for FICC in times of stress by allowing FICC to retain the respective Division's Clearing Fund, its critical prefunded resource, while charging loss allocations. FICC believes doing so would allow FICC to cover the respective Division's current credit exposures to its Members at all times. By retaining the GSD and MBSD Clearing Funds as proposed, FICC could use the Clearing Funds to secure the performance obligations of Members to their respective Division, including their payment obligation for any loss allocation, while maintaining access to prefunded resources. By being able to manage the respective Division's current credit exposures throughout the loss allocation process, FICC would be able to continue to provide its critical operations and services during what would be expected to be a stressful period.

⁴³ Supra note 19.

As proposed, Tier One Netting Members or Tier One Members, as applicable, would have two (2) Business Days after FICC issues a first round Loss Allocation Notice to pay the amount specified in any such notice.44 On a subsequent round (i.e., if the first round did not cover the entire loss of the Event Period because FICC was only able to allocate up to the round cap), these members would also have two (2) Business Days after notice by FICC to pay their loss allocation amounts (again subject to their Loss Allocation Caps), unless the members have notified (or will timely notify) FICC of their election to withdraw from membership with respect to a prior loss allocation round.

Under the proposal, if a Tier One Netting Member or Tier One Member, as applicable, fails to make its required payment in respect of a Loss Allocation Notice by the time such payment is due, FICC would have the right to proceed against such member as a Defaulting Member that has failed to satisfy an obligation in accordance with proposed Section 6 of GSD Rule 4 or MBSD Rule 4 described above. Members who wish to withdraw from membership would be required to comply with the requirements in proposed Section 7b of GSD Rule 4 and MBSD Rule 4, described further below. Specifically, proposed Section 7 of GSD Rule 4 and MBSD Rule 4 would provide that if, after notifying FICC of its election to withdraw from membership pursuant to proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, the Tier One Netting Member or Tier One Member, as applicable, fails to comply with the provisions of proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, its notice of withdrawal would be deemed void and any further losses resulting from the applicable Event Period may be allocated against it as if it had not given such notice.

FICC is proposing to delete the provisions in the current GSD Rule 4 and MBSD Rule 4 that require FICC to assess the Required Fund Deposit maintained by each Tier One Netting Member or Tier One Member, as applicable, an amount up to \$50,000, in an equal basis per such member, before allocating losses to Tier One Netting Members or Tier One Members, as applicable, ratably, in accordance with each such member's Required Fund Deposit and Average Required FICC Clearing Fund Deposit or Average Required Clearing Fund Deposit, as applicable. FICC believes that in the event of a loss or liability, this assessment is unlikely to alleviate the

need for loss mutualization and creates an unnecessary administrative burden for each Division. FICC believes that moving straight to the loss mutualization described herein would be more practical. This proposed change would also streamline each Division's loss allocation waterfall processes and align such processes with those of the other DTCC Clearing Agencies.

Tier Two Members

FICC is not proposing any substantive change to the provisions regarding Tier Two Members in current Section 7 of GSD Rule 4 and MBSD Rule 4, except to (i) add a subheading of "Tier Two Members" in the beginning of these provisions for ease of identification and (ii) add a paragraph that makes it clear that if a Tier Two Member fails to make its required payment in respect of a Loss Allocation Notice by the time such payment is due, FICC would have the right to proceed against such member as a Defaulting Member that has failed to satisfy an obligation in accordance with proposed Section 6 of GSD Rule 4 or MBSD Rule 4 described above, consistent with the proposed change regarding Tier One Netting Members or Tier One Members, as applicable.

Withdrawal From Membership

Proposed Section 7b of GSD Rule 4 and MBSD Rule 4 would include the provisions regarding withdrawal from membership currently covered by Section 7(g) of GSD Rule 4 and MBSD Rule 4. FICC believes that relocating the provisions on withdrawal from membership as it pertains to loss allocation, so that it comes right after the section on the loss allocation waterfall, would provide for the better organization of GSD Rule 4 and MBSD Rule 4. As proposed, the subheading for Section 7b of GSD Rule 4 and MBSD Rule 4 would read "Withdrawal Following Loss Allocation."

Currently, Section 7(g) of GSD Rule 4 and MBSD Rule 4 provides that a member may, pursuant to current Section 13 of GSD Rule 3 or MBSD Rule 3, notify FICC by the Close of Business on the Business Day on which a payment in an amount necessary to cover losses allocated to such member after the application of its Required Fund Deposit is due, of its election to terminate its membership and thereby avail itself of a cap on loss allocation, which is currently its Required Fund Deposit as fixed on the Business Day the pro rata charge loss allocation notification is provided to such member.

As stated above, under the proposed rule change, Section 7 of GSD Rule 4

and MBSD Rule 4 would provide that a Tier One Netting Member or a Tier One Member, as applicable, who wishes to withdraw from membership in respect of a loss allocation round must provide notice of its election to withdraw ("Loss Allocation Withdrawal Notice'') within five (5) Business Days from the issuance of the first Loss Allocation Notice in any round.45 In order to avail itself of its Loss Allocation Cap, such member would need to follow the requirements in proposed Section 7b of GSD Rule 4 and MBSD Rule 4, as applicable, which would provide that such member must: (i) Specify in its Loss Allocation Withdrawal Notice an effective date for withdrawal from membership, which date shall not be prior to the scheduled final settlement date of any remaining obligations owed by the member to FICC, unless otherwise approved by FICC, and (ii) as of the time of such member's submission of the Loss Allocation Withdrawal Notice, cease submitting transactions to FICC for processing, clearance or settlement, unless otherwise approved by FICC.

Proposed Section 7b of GSD Rule 4 and MBSD Rule 4 would provide that a Tier One Netting Member or a Tier One Member, as applicable, that withdraws in compliance with the requirements of proposed Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, would nevertheless remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under proposed GSD Rule 4 or MBSD Rule 4, as applicable; however, the Tier One Netting Member's or Tier One Member's, as applicable, aggregate obligation would be limited to the amount of its Loss Allocation Cap (as fixed in the round for which it withdrew).

FICC is proposing to include a sentence in proposed Section 7b of GSD Rule 4 and MBSD Rule 4 to make it clear that if the Tier One Netting Member or Tier One Member, as applicable, fails to comply with the requirements set forth in that section, its Loss Allocation Withdrawal Notice will be deemed void, and such member will remain subject to further loss allocations pursuant to proposed Section 7 of GSD Rule 4 and MBSD Rule 4 as if it had not given such notice.

For better organization of the subject matter, FICC is also proposing to move the provision that covers members' obligations to eliminate any deficiency in their Required Fund Deposits from the last sentence in the first paragraph of current Section 7(g) of GSD Rule 4

⁴⁴ Supra note 22.

⁴⁵ Supra note 19.

and MBSD Rule 4 to proposed Section 9 of GSD Rule 4 and MBSD Rule 4.

Section 8

As proposed, Section 8 of GSD Rule 4 and MBSD Rule 4 would cover the provisions on the return of a member's Clearing Fund deposit that are currently covered by Section 10 of GSD Rule 4 and MBSD Rule 4. Proposed Section 8's subheading would be "Return of Members' Clearing Fund Deposits."

FICC is proposing changes to streamline and enhance the clarity and readability of this section, including adding language to clarify that a member's obligations to FICC would include both matured as well as contingent obligations, but is otherwise retaining the substantive provisions of this section.

Section 9

FICC is proposing to renumber Section 8 of GSD Rule 4 and MBSD Rule 4, which addresses the timing of members' payment of the respective Division's Clearing Fund. Under the proposal, this section would be renumbered as Section 9 of GSD Rule 4 and MBSD Rule 4 and retitled to "Initial Required Fund Deposit and Changes in Members' Required Fund Deposits" to better reflect the subject matter of this section.

Currently, Section 8 of GSD Rule 4 and MBSD Rule 4 requires members to satisfy any increase in their Required Fund Deposit requirement within such time as FICC requires. FICC is proposing to clarify that at the time the increase becomes effective, the member's obligations to FICC will be determined in accordance with the increased Required Fund Deposit whether or not the member has satisfied such increased amount. FICC is also proposing to add language to clarify that (i) if FICC applies a GSD Netting Member's or an MBSD Clearing Member's Clearing Fund deposits as permitted pursuant to GSD Rule 4 or MBSD Rule 4, as applicable, FICC may take any and all actions with respect to the GSD Netting Member's or MBSD Clearing Member's Actual Deposit, including assignment, transfer, and sale of any Eligible Clearing Fund Securities, that FICC determines is appropriate, and (ii) if such application results in any deficiency in the GSD Netting Member's or MBSD Clearing Member's, as applicable, Required Fund Deposit, such member shall immediately replenish it. These clarifications are consistent with the Divisions' rights as set forth in current Sections 4 and 11 of GSD Rule 4 and current Sections 4 and 11 of MBSD Rule 4. In addition, the provisions in clause

(ii) of the previous sentence is consistent with the requirements in current Section 1 of GSD Rule 4 and MBSD Rule 4 that a member must maintain its Required Fund Deposit.

As discussed above, for better organization of the subject matter, FICC is proposing to move the provision that covers members' obligations to eliminate any deficiency in their Required Fund Deposits from the last sentence in the first paragraph of current Section 7(g) of GSD Rule 4 and MBSD Rule 4 to proposed Section 9 of GSD Rule 4 and MBSD Rule 4.

Section 10

Currently, Section 9 of GSD Rule 4 and MBSD Rule 4 addresses situations where a member has excess on deposit in the Clearing Fund (i.e., amounts above its Required Fund Deposit). The current provision provides that FICC will notify a member of any Excess Clearing Fund Deposit as FICC determines from time to time. Upon the request of a member, FICC will return an excess amount requested by a member that follows the formats and timeframe established by FICC for such request. The current provision makes clear that FICC may, in its discretion, withhold any or all of a member's Excess Clearing Fund Deposit (i) if the member has an outstanding payment obligation to FICC, (ii) if FICC determines that the member's anticipated activity over the next 90 calendar days may reasonably be expected to be materially different than the prior 90 calendar days, or (iii) if the member has been placed on the Watch List. Section 9 also makes clear that the return of an Excess Clearing Fund Deposit to any member is subject to (i) such return of Excess Clearing Fund Deposit not being done in a manner that would cause the member to violate any other section of the Rules, (ii) such return not reducing the amount of the member's Cross-Guaranty Repayment Deposit to the Clearing Fund below the amount required to be maintained by the member pursuant to GSD Rule 41 or MBSD Rule 32, as applicable, and (iii) with respect to GSD Members only, such return not reducing the amount of a GSD Member's Cross-Margining Repayment Deposit to the Clearing Fund below the amount required to be maintained by the GSD Member pursuant to GSD Rule 43.

FICC is proposing to renumber Section 9 as Section 10 for both GSD Rule 4 and MBSD Rule 4 and to retitle its subheading to "Excess Clearing Fund Deposits" to better reflect the subject matter of the provisions. FICC is not proposing any changes to this section except to streamline and clarify the provisions as well as to align GSD Rule 4 and MBSD Rule 4, including adding a sentence to clarify that nothing in this section limits FICC's rights under Section 7 of GSD Rule 3 or Section 6 of MBSD Rule 3, as applicable.

Section 11

Current Section 11 of GSD Rule 4 and MBSD Rule 4 provides that FICC has certain rights with respect to the Clearing Fund. FICC is proposing to add a sentence which would make it clear that GSD Rule 4 or MBSD Rule 4, as applicable, would govern in the event of any conflict or inconsistency between such rule and any agreement between FICC and any member. FICC believes that this proposed change would facilitate members' understanding of the Rules and their obligations thereunder. It would also align the Rules with the Rules and Procedures of NSCC so as to provide consistent treatment for firms that are members of both FICC and $NSCC.^{46}$ Furthermore, in order to enhance the readability and clarity, FICC is proposing a number of changes to streamline the language in this section.

(ii) Other Proposed Rule Changes

FICC is proposing changes to GSD Rule 1 (Definitions), GSD Rule 3 (Ongoing Membership Requirements), GSD Rule 3A (Sponsoring Members and Sponsored Members), GSD Rule 3B (Centrally Cleared Institutional Triparty Service), GSD Rule 13 (Funds-Only Settlement), GSD Rule 18 (Special Provisions for Repo Transactions), GSD Rule 21A (Wind-Down of a Netting Member), GSD Rule 22B (Corporation Default), GSD Rule 41 (Cross Guaranty Agreements), GSD Rule 43 (Cross-Margining Arrangements), GSD Board Interpretations and Statements of Policy, and GSD Interpretive Guidance with Respect to Watch List Consequences. FICC is also proposing changes to MBSD Rule 1 (Definitions), MBSD Rule 3 (Ongoing Membership Requirements), MBSD Rule 5 (Trade Comparison), MBSD Rule 11 (Cash Settlement), MBSD Rule 17A (Corporation Default), MBSD Rule 32 (Cross Guaranty Agreements), and MBSD Interpretive Guidance with Respect to Watch List Consequences. FICC is proposing changes to these Rules in order to conform them with the proposed changes to GSD Rule 4 and MBSD Rule 4, as applicable, as well as

⁴⁶ See Section 12 of Rule 4 in NSCC's Rules and Procedures, available at http://www.dtcc.com/~/media/Files/Downloads/legal/rules/nscc_rules.pdf.

to make certain technical changes to these Rules, as further described below.

Adding Defined Terms

Specifically, FICC is proposing to add the following defined terms to GSD Rule 1, in alphabetical order: Actual Deposit, Average RFD, CCIT Member Termination Date, CCIT Member Voluntary Termination Notice, Clearing Fund Cash, Corporate Contribution, Declared Non-Default Loss Event, Defaulting Member Event, Event Period, Excess Clearing Fund Deposit, Former Sponsored Members, Lender, Loss Allocation Cap, Loss Allocation Notice, Loss Allocation Withdrawal Notice, Sponsored Member Termination Date, Sponsored Member Voluntary Termination Notice, Sponsoring Member Termination Date, Sponsoring Member Voluntary Termination Notice, Termination Date, and Voluntary Termination Notice.

FICC is also proposing to add the following defined terms to MBSD Rule 1, in alphabetical order: Actual Deposit, Average RFD, Clearing Fund Cash, Corporate Contribution, Declared Non-Default Loss Event, Defaulting Member Event, Event Period, Excess Clearing Fund Deposit, Lender, Loss Allocation Cap, Loss Allocation Notice, Loss Allocation Withdrawal Notice, Termination Date, and Voluntary Termination Notice.

Technical Changes

In addition, FICC is proposing technical changes (i) to delete the defined term "The Corporation" in GSD Rule 1 and replace it with "Corporation" in GSD Rule 1, (ii) to correct cross-references in Section 8 of MBSD Rule 5 and the definition of "Legal Risk" in GSD Rule 1, (iii) to update references to sections that would be changed under this proposal in Section 12 of GSD Rule 3, Sections 10 and 12(a) of GSD Rule 3A, Section 3(f) of GSD Rule 18, GSD Rule 21A, Sections 3(a), 3(b) and 4 of GSD Rule 41, Section 6 of GSD Rule 43, GSD Interpretive Guidance with Respect to Watch List Consequences, Sections 11, 14, and 15 of MBSD Rule 3, Section 3(b) of MBSD Rule 32, and MBSD Interpretive Guidance with Respect to Watch List Consequences, (iv) to update the reference to a subheading that would be changed under this proposal in Section 7 of GSD Rule 3B, and (v) to delete a reference to the Cross-Margining Agreement between FICC and NYPC that is no longer in effect. FICC believes that these proposed technical changes would ensure the Rules remain clear and accurate, which would in turn

allow Members to readily understand their obligations under the Rules.

Voluntary Termination

FICC is also proposing changes to the voluntary termination provisions in GSD Rule 3, GSD Rule 3A, GSD Rule 3B, and MBSD Rule 3 in order to ensure that termination provisions in the GSD Rules and MBSD Rules, whether voluntary or in response to a loss allocation, are consistent with one another to the extent appropriate.

Currently, the voluntary termination provisions in GSD Rule 3, GSD Rule 3A, GSD Rule 3B, and MBSD Rule 3 generally provide that a member may elect to terminate its membership by providing FICC with 10 days written notice of such termination. Such termination will not be effective until accepted by FICC, which shall be no later than 10 Business Days after the receipt of the notice. FICC's acceptance shall be evidenced by a notice to FICC's members announcing the member's termination and the effective date of the termination ("Termination Date"), and that the terminating member will no longer be eligible to submit transactions to FICC as of the Termination Date. 47 This provision also provides that a member's voluntary termination of membership shall not affect its obligations to FICC.

Where appropriate, FICC is proposing changes to align the voluntary termination provisions in Section 13 of GSD Rule 3, Sections 2(i) and 3(e) of GSD Rule 3A, Section 6 of GSD Rule 3B, and Section 14 of MBSD Rule 3 with the proposed new Section 7b of GSD Rule 4 and MBSD Rule 4, given that they all address termination of membership. Specifically, in Section 13 of GSD Rule 3, FICC is proposing that when a GSD Member elects to voluntarily terminate its membership by providing FICC a written notice of such termination ("Voluntary Termination Notice"), the GSD Member must specify in its Voluntary Termination Notice a desired date for its withdrawal from membership; provided, however, if the GSD Member is terminating its membership in GSD (i.e., not terminating its membership just in the Netting System), such date shall not be prior to the scheduled final settlement date of any remaining obligation owed by the GSD Member to FICC as of the time such Voluntary Termination Notice is submitted to FICC, unless otherwise approved by FICC. FICC is proposing to delete the provision that requires a

member to provide FICC with 10 days written notice of the member's termination; however, FICC is retaining the provision that states termination will not be effective until accepted by FICC,⁴⁸ which shall be no later than 10 Business Days after the receipt of the notice. FICC is also retaining the provision that states FICC's acceptance shall be evidenced by a notice to FICC's members announcing the member's termination and the Termination Date, and that the terminating member will no longer be eligible to submit transactions to FICC as of the Termination Date.

As an example, Member A submits a Voluntary Termination Notice to GSD on April 1st indicating its desired termination date is June 15th. GSD would accept such termination request by issuing a notice to GSD Members within 10 Business Days from April 1st; such notice would provide that the effective date of Member A's GSD membership termination is June 15th. In contrast, if Member A submits a Voluntary Termination Notice on April 1st and indicates its desired termination date is April 5th, GSD would either (i) accept such termination notice by issuing a notice to GSD Members on or before April 5th, and such notice would provide that the effective date of Member A's GSD membership termination is April 5th or (ii) if GSD requires additional time to process the termination, GSD would accept such termination notice by issuing notice to GSD Members after April 5th but still within 10 Business Days from April 1st; and such notice would provide that the effective date of Member A's GSD membership termination as a date after April 5th.

The proposed change to Section 13 of GSD Rule 3 would also provide that if any trade is submitted to FICC either by the withdrawing GSD Member or its authorized submitter that is scheduled to settle on or after the Termination Date, the GSD Member's Voluntary Termination Notice would be deemed void and the GSD Member would remain subject to the GSD Rules as if it had not given such notice. Furthermore, FICC is proposing to add a sentence to Section 13 of GSD Rule 3 to refer GSD Members to Section 8 of GSD Rule 4

⁴⁷ Account(s) of a terminating member would generally be deactivated before the open of business on the Termination Date.

⁴⁸ Unlike the Voluntary Termination Notice, the Loss Allocation Withdrawal Notice as proposed in Section 7b of GSD Rule 4 and MBSD Rule 4 does not require explicit acceptance by FICC to be effective. FICC believes that requiring explicit acceptance of the Loss Allocation Withdrawal Notice could complicate the loss allocation process and potentially result in membership withdrawal being delayed as well as detract from the objective to have FICC know on a timely basis which members would remain subject to the subsequent rounds of loss allocation.

regarding provisions on the return of a GSD Member's Clearing Fund deposit and to specify that if an Event Period were to occur after a Tier One Netting Member has submitted its Voluntary Termination Notice but prior to the Termination Date, in order for such Tier One Netting Member to benefit from its Loss Allocation Cap pursuant to Section 7 of GSD Rule 4, the Tier One Netting Member would need to comply with the provisions of Section 7b of GSD Rule 4 and submit a Loss Allocation Withdrawal Notice, which notice, upon submission, would supersede and void any pending Voluntary Termination Notice previously submitted by the Tier One Netting Member. 49 As an example, if an Event Period occurs after submission of the Voluntary Termination Notice by a Tier One Netting Member or Tier One Member, as applicable, but prior to the Termination Date, and the Tier One Netting Member or Tier One Member, as applicable, does not subsequently submit a Loss Allocation Withdrawal Notice as proposed in Section 7b of GSD Rule 4 or MBSD Rule 4, as applicable, then the Tier One Netting Member or Tier One Member, as applicable, would not benefit from its Loss Allocation Cap, i.e., the Tier One Netting Member or Tier One Member, as applicable, would remain obligated for its pro rata share of losses and liabilities with respect to any Event Period that commenced prior to the Termination Date.

Parallel changes are also being proposed to Section 2(i) of GSD Rule 3A and Section 14 of MBSD Rule 3 with additional language in Section 2(i) of GSD Rule 3A and Section 14 of MBSD Rule 3 making it clear that the acceptance by FICC of a member's Voluntary Termination Notice shall be no later than ten (10) Business Days after the receipt of such notice from the member, in order to provide certainty to members as well as to align these sections with the current Section 13 of GSD Rule 3.

With respect to Section 3(e) of GSD Rule 3A and Section 6 of GSD Rule 3B, changes similar to the ones described above in the previous paragraph are also being proposed for Sponsored Members and CCIT Members, except there would be no references to the return of a member's Clearing Fund deposits and to

Loss Allocation Caps because they would not apply to these member types. In addition, FICC is proposing a technical change in Section 6 of GSD Rule 3B to reflect a defined term that would be changed under this proposal.

Other MBSD Proposed Rule Changes

FICC is proposing to delete Section 15 of MBSD Rule 3 because FICC believes that this section is akin to a loss allocation provision and therefore would no longer be necessary under the proposed rule change, as the scenarios envisioned by Section 15 of MBSD Rule 3 would be governed by the proposed loss allocation provisions in MBSD Rule 4.

Other GSD Proposed Rule Changes

Under the proposal, Section 12(c) of GSD Rule 3A would also be revised to incorporate the concept of the Loss Allocation Cap and to reference the applicable proposed sections in GSD Rule 4 that would apply when a Sponsoring Member elects to terminate its status as a Sponsoring Member.

FICC is also proposing to delete an Interpretation of the Board of Directors of the Government Securities Clearing Corporation (the predecessor to GSD), which currently clarifies certain provisions of GSD Rule 4 and the extent to which the GSD Clearing Fund and other required deposits of GSD Netting Members may be applied to a loss or liability incurred by FICC. FICC is proposing this deletion because this interpretation would no longer be necessary following the proposed rule change. This is because the proposed rule change to GSD Rule 4 would cover the extent to which the GSD Clearing Fund and other collateral or assets of GSD Netting Members would be applied to a loss or liability incurred by FICC.

Other GSD Proposed Rule Changes and MBSD Proposed Rule Changes

FICC is proposing changes to Section 11 of GSD Rule 4 and MBSD Rule 4. Specifically, FICC is proposing to replace "letters of credit" with "Eligible Letters of Credit," which is already a defined term in the Rules. In addition, FICC is proposing to specify that a reference to 30 days means 30 calendar days.

FICC is proposing to delete "Remaining Loss" and "Other Loss" in Sections 12(a) and 12(b) of GSD Rule 3A, Section 5 of GSD Rule 13, Section 4 of GSD Rule 41, Section 6 of GSD Rule 43, Section 9(o) of MBSD Rule 11, and Section 4 of MBSD Rule 32 because these terms would no longer be used under the proposed GSD Rule 4 and MBSD Rule 4, and to add clarifying language that conforms to the proposed changes to GSD Rule 4 and MBSD Rule 4.

In addition, FICC is proposing changes to GSD Rule 22B (Corporation Default) and MBSD Rule 17A (Corporation Default). FICC is proposing to relocate the interpretational parenthetical in each rule to come right after the reference to GSD Rule 22A and MBSD Rule 17. FICC is proposing this change because, in the event of a Corporation Default, the portfolio of each GSD Member or MBSD Member, as applicable, would be closed out in the same way as the portfolio of a GSD Defaulting Member or MBSD Defaulting Member, i.e., by applying the close out procedures of GSD Rule 22A (Procedures for When the Corporation Ceases to Act) or MBSD Rule 17 (Procedures for When the Corporation Ceases to Act), as applicable. În addition, in the proposed GSD Rule 22B and MBSD Rule 17A, FICC is proposing to add a reference to the loss allocation provisions of GSD Rule 4 and MBSD Rule 4 and delete references to specific sections of GSD Rule 4 and MBSD Rule 4, because those sections are being modified under the proposed rule change.

Member Outreach

Beginning in August 2017, FICC conducted outreach to Members in order to provide them with advance notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

Implementation Timeframe

Pending Commission approval, FICC expects to implement this proposal within two (2) Business Days after approval. Members would be advised of the implementation date of this proposal through issuance of a FICC Important Notice.

2. Statutory Basis

FICC believes that the proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, FICC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act ⁵⁰ and Rules 17Ad–22(e)(13) and 17Ad–22(e)(23)(i),⁵¹ each as promulgated

⁴⁹ Loss Allocation Caps would not apply to Tier Two Netting Members and Tier Two Members because the loss allocation obligations of Tier Two Netting Members and Tier Two Members are already capped to the liquidation losses that resulted from their trading activity with the Defaulting Member. Tier Two Netting Members and Tier Two Members are required to pay their loss allocation obligations in full.

⁵⁰ 15 U.S.C. 78q–1(b)(3)(F).

^{51 17} CFR 240.17Ad-22(e)(13) and (e)(23)(i).

under the Act, for the reasons described

Section 17A(b)(3)(F) of the Act requires that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in the custody or control of each Division or for which it is responsible.52 The proposed rule changes to (1) modify the calculation and application of FICC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the member withdrawal process in connection with the loss allocation process, and (4) implement a revised "look-back" period to calculate a member's loss allocation obligation and its Loss Allocation Cap, taken together, are intended to enhance the overall resiliency of each Division's loss

allocation process.

By modifying the calculation of FICC's corporate contribution, FICC would apply a mandatory fixed percentage of its General Business Risk Capital Requirement (as compared to the current Rules which provide for "up to" a percentage of retained earnings), which would provide greater transparency and accessibility to members as to how much FICC would contribute in the event of a loss or liability. By modifying the application of FICC's corporate contribution to apply to Declared Non-Default Loss Events, in addition to Defaulting Member Events, on a mandatory basis, FICC would expand the application of its corporate contribution beyond losses and liabilities from member defaults, which would better align the interests of FICC with those of its respective Division's members by stipulating a mandatory application of the Corporate Contribution to a Declared Non-Default Loss Event prior to any allocation of the loss among Tier One Netting Members or Tier One Members, as applicable. Taken together, these proposed rule changes would enhance the overall resiliency of each Division's loss allocation process by enhancing the calculation and application of FICC's Corporate Contribution, which is one of the key elements of each Division's loss allocation process. Moreover, by providing greater transparency and accessibility to members, as stated above, the proposed rule changes regarding the Corporate Contribution, including the proposed replenishment

period and proposed allocation of FICC Corporate Contribution between Divisions, would allow members to better assess the adequacy of each Division's loss allocation process.

By introducing the concept of an Event Period, FICC would be able to group Defaulting Member Events and Declared Non-Default Loss Events occurring in a period of ten (10) Business Days for purposes of allocating losses to members. FICC believes that the Event Period would provide a defined structure for the loss allocation process to encompass potential sequential Defaulting Member Events or Declared Non-Default Loss Events that are likely to be closely linked to an initial event and/or market dislocation episode. Having this structure would enhance the overall resiliency of FICC's loss allocation process because FICC would be better equipped to address losses that may arise from multiple Defaulting Member Events and/or Declared Non-Default Loss Events that arise in quick succession. Moreover, the proposed Event Period structure would provide certainty for members concerning their maximum exposure to mutualized losses with respect to such events.

By introducing the concept of "rounds" (and accompanying Loss Allocation Notices) and applying this concept to the timing of loss allocation payments and the member withdrawal process in connection with the loss allocation process, FICC would (i) set forth a defined amount that it would allocate to members during each round (i.e., the round cap), (ii) advise members of loss allocation obligation information as well as round information through the issuance of Loss Allocation Notices, and (iii) provide members with the option to limit their loss allocation exposure after the issuance of the first Loss Allocation Notice in each round. These proposed rule changes would enhance the overall resiliency of FICC's loss allocation process because they would enable FICC to continue the loss allocation process in successive rounds until all of FICC's losses are allocated and enable FICC to identify continuing members for purposes of calculating subsequent loss allocation obligations in successive rounds. Moreover, the proposed rule changes would define for members a clear manner and process in which they could cap their loss allocation exposure to FICC.

By implementing a revised "lookback" period to calculate a member's loss allocation obligations and its Loss Allocation Cap, FICC would be able to capture a full calendar quarter of the member's activities and smooth out the

impact from any abnormalities and/or arbitrariness that may have occurred. By determining a member's loss allocation obligations based on the average of its Required Fund Deposit over a look-back period and its Loss Allocation Cap based on the greater of its Required Fund Deposit or the average thereof over a look-back period, FICC would be able to calculate a member's pro rata share of losses and liabilities based on the amount of risk that the member brings to FICC. These proposed rule changes would enhance the overall resiliency of each Division's loss allocation process because they would align a member's loss allocation obligation and its Loss Allocation Cap with the amount of risk that the member brings to FICC.

Taken together, the foregoing proposed rule changes would establish a stronger (for all the reasons discussed above) and clearer loss allocation process for each Division, which FICC believes would allow each Division to take timely action to address losses. The ability to timely address losses would allow each Division to continue to meet its clearance and settlement obligations, especially in circumstances that may involve a series of substantially contemporaneous loss events. Therefore, FICC believes that these proposed rule changes would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

By deleting certain vague and imprecise limiting language that could be interpreted as impairing FICC's ability to access the MBSD Clearing Fund to cover losses and liabilities incident to its clearance and settlement business outside the context of an MBSD Defaulting Member Event, as well as to cover certain liquidity needs, the proposed rule change to amend FICC's permitted use of MBSD Clearing Fund would enhance FICC's ability to ensure that it can continue its operations and clearance and settlement services in an orderly manner in the event that it would be necessary or appropriate for FICC to access MBSD Clearing Fund deposits to address losses, liabilities or liquidity needs to meet its settlement obligations. Therefore, FICC believes that this proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

Rule 17Ad-22(e)(13) under the Act requires, in part, that FICC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure each

^{52 15} U.S.C. 78q-1(b)(3)(F).

Division has the authority and operational capacity to take timely action to contain losses and continue to meet its obligations.53 As described above, the proposed rule changes to (1) modify the calculation and application of FICC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the member withdrawal process in connection with the loss allocation process, and (4) implement a revised ''look-back'' period to calculate a member's loss allocation obligation and its Loss Allocation Cap, taken together, are designed to enhance the resiliency of each Division's loss allocation process. Having a resilient loss allocation process would help ensure that each Division can effectively and timely address losses relating to or arising out of either the default of one or more members or one or more nondefault loss events, which in turn would help each Division contain losses and continue to meet its clearance and settlement obligations. Therefore, FICC believes that the proposed rule changes to enhance the resiliency of each Division's loss allocation process are consistent with Rule 17Ad-22(e)(13) under the Act.

Rule 17Ad-22(e)(23)(i) under the Act requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to publicly disclose all relevant rules and material procedures, including key aspects of each Division's default rules and procedures.⁵⁴ The proposed rule changes to (i) align the loss allocation rules of the DTCC Clearing Agencies, (ii) improve the overall transparency and accessibility of the provisions in the Rules governing loss allocation and (iii) make conforming and technical changes, would not only ensure that each Division's loss allocation rules are, to the extent practicable and appropriate, consistent with the loss allocation rules of other DTCC Clearing Agencies, but also would help to ensure that each Division's loss allocation rules are transparent and clear to members. Aligning the loss allocation rules of the DTCC Clearing Agencies would provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and clear loss allocation rules would enable members to better understand the key aspects of each

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe that the proposed rule changes to enhance the resiliency of each Division's loss allocation process would impact competition.⁵⁵ As described above, the proposed rule changes to (1) modify the calculation and application of FICC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the member withdrawal process in connection with the loss allocation process, and (4) implement a revised "look-back" period to calculate a member's loss allocation obligation and its Loss Allocation Cap, taken together, are intended to enhance the overall resiliency of each Division's loss allocation process, and would apply equally to all members. While the proposed rule changes would amend the manner in which FICC's corporate contribution and loss allocation are calculated and applied, such proposed rule changes would maintain FICC's current core loss allocation waterfall in the case of a loss relating to or arising out of the default of a member for whom FICC has ceased to act following application of the defaulting member's resources, i.e., FICC's corporate contribution and loss allocation among members. With respect to a loss or liability arising from a non-default loss event, the proposed rule changes clarify FICC's contribution to such loss and liability, but, as with losses and liabilities arising from a member default event, the proposed rule changes would maintain the loss mutualization requirement under the current GSD Rules and MBSD Rules. While the calculation of the loss obligations associated with non-default losses would change under the proposal, the FICC Divisions would maintain this aspect of the loss allocation waterfall (i.e., loss mutualization among members for non-default losses). Based on the foregoing, FICC believes that these

FICC also does not believe that the proposed rule changes to (i) align the

Division's default rules and procedures and provide members with increased predictability and certainty regarding their exposures and obligations. As such, FICC believes that the proposed rule changes to align the loss allocation rules of the DTCC Clearing Agencies as well as to improve the overall transparency and accessibility of each Division's loss allocation rules are consistent with Rule 17Ad–22(e)(23)(i) under the Act.

proposed rule changes to enhance the resiliency of each Division's loss allocation process would not have any impact on competition.

FICC does not believe the proposed rule change to delete certain vague and imprecise limiting language regarding FICC's use of MBSD Clearing Fund would impact competition.⁵⁶ This proposed rule change would enhance FICC's ability to ensure that it can continue its operations and clearance and settlement services in an orderly manner in the event that it would be necessary or appropriate for FICC to access MBSD Clearing Fund deposits to address losses, liabilities or liquidity needs to meet its settlement obligations. In the event that it would be necessary or appropriate for FICC to access MBŠD Clearing Fund deposits, FICC's use of MBSD Clearing Fund deposits would remain subject to the parameters in the proposed rule that limit FICC's use of MBSD Clearing Fund, i.e., (A) to secure each MBSD Member's performance of obligations to FICC, (B) to provide liquidity to FICC to meet its settlement obligations, and (C) for certain investments. FICC does not believe that FICC's utilization of MBSD Clearing Fund under these parameters would impact competition. Specifically, FICC does not believe that using MBSD Clearing Fund to secure each MBSD Member's performance of obligations to FICC and for certain investments would have an impact on the MBSD Members because the fund and/or investments are still being held by FICC. With respect to FICC's use of MBSD Clearing Fund pursuant to parameter (B), FICC believes that there may be an impact on MBSD Members if FICC uses the MBSD Clearing Fund for more than 30 calendar days. This is because FICC would then consider the amount of MBSD Clearing Fund used but not yet repaid as a loss to the MBSD Clearing Fund incurred as a result of a Defaulting Member Event and immediately allocate such loss in accordance with the proposal. However, because loss allocation among the MBSD Members would be based on the Average RFDs of those MBSD Members, any loss allocation among MBSD Members would affect MBSD Members in proportion to the amount of risks they bring to FICC, as represented by their Average RFDs. Based on the foregoing, FICC does not believe that the proposed deletion of the limiting language regarding FICC's use of MBSD Clearing Fund would have any impact on competition.

^{53 17} CFR 240.17Ad-22(e)(13).

^{54 17} CFR 240.17Ad-22(e)(23)(i).

loss allocation rules of the DTCC Clearing Agencies, (ii) increase the transparency and accessibility of provisions in the Rules governing loss allocation, and (iii) make conforming and technical changes, would impact competition.57 These changes would apply equally to all members. Alignment of the loss allocation rules of the DTCC Clearing Agencies are intended to increase the consistency of the Rules with the rules of other DTCC Clearing Agencies in order to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and accessible provisions in the Rules governing loss allocation are intended to improve the readability and clarity of the Rules regarding the loss allocation process. Making conforming and technical changes to ensure the Rules remain clear and accurate would facilitate members' understanding of the Rules and their obligations thereunder. As such, FICC believes that these proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to this proposed rule change have not been solicited or received. FICC will notify the Commission of any written comments received by FICC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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–FICC–2017–022 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–FICC–2017–022. 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 website (*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 website 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 FICC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-FICC-2017-022 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 58

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15366 Filed 7–18–18; 8:45 am] BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83630; File No. SR-FICC-2017-021]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Adopt a Recovery & Wind-down Plan and Related Rules

July 13, 2018.

On December 18, 2017, Fixed Income Clearing Corporation ("FICC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–FICC–2017–021 ("Proposed Rule Change") to adopt a recovery and wind-

down plan and related rules.¹ The Proposed Rule Change was published for comment in the **Federal Register** on January 8, 2018.² On February 8, 2018, the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.3 On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change. 4 On June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to

115 U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively. On December 18, 2017, FICC filed the Proposed Rule Change as advance notice SR-FICO 2017-805 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release No. 82580 (January 24, 2018), 83 FR 4341 (January 30, 2018) (SR-FICC-2017-805). On April 10, 2018, the Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Commission's Request for Additional Information," available at https:// www.sec.gov/rules/sro/ficc-an.htm. On June 28, 2018, FICC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, FICC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/ficc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 U.S.C $5465(e)(1)(\bar{E})$ and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at https://www.sec.gov/ rules/sro/ficc-an.htm. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

² Securities Exchange Act Release No. 82431 (January 2, 2018), 83 FR 871 (January 8, 2018) (SR–FICC–2017–021).

³ Securities Exchange Act Release No. 82669 (February 8, 2018), 83 FR 6653 (February 14, 2018) (SR-DTC-2017-021; SR-FICC-2017-021; SR-NSCC-2017-017).

⁴ Securities Exchange Act Release No. 82913 (March 20, 2018), 83 FR 12997 (March 26, 2018) (SR-FICC-2017-021).

^{58 17} CFR 200.30-3(a)(12).

approve or disapprove the Proposed Rule Change.⁵ On June 28, 2018, FICC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.⁶ As of the date of this release, the Commission has not received any comments on the Proposed Rule Change.

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by FICC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The Proposed Rule Change of FICC proposes to adopt the Recovery & Winddown Plan of FICC ("R&W Plan" or "Plan"). The R&W Plan would be maintained by FICC in compliance with Rule 17Ad–22(e)(3)(ii) under the Act by providing plans for the recovery and orderly wind-down of FICC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described below.⁷

The Proposed Rule Change would also propose to (1) amend FICC's Government Securities Division ("GSD") Rulebook ("GSD Rules") in order to (a) adopt Rule 22D (Wind-down of the Corporation) and Rule 50 (Market Disruption and Force Majeure), and (b) make conforming changes to Rule 3A (Sponsoring Members and Sponsored Members), Rule 3B (Centrally Cleared Institutional Triparty Service) and Rule 13 (Funds-Only Settlement) related to the adoption of these Proposed Rules to the GSD Rules; (2) amend FICC's Mortgage-Backed Securities Division ("MBSD," and, together with GSD, the "Divisions") Clearing Rules ("MBSD Rules'') in order to (a) adopt Rule 17B (Wind-down of the Corporation) and Rule 40 (Market Disruption and Force Majeure); and (b) make conforming changes to Rule 3A (Cash Settlement Bank Members) related to the adoption

of these Proposed Rules to the MBSD Rules; and (3) amend Rule 1 of the Electronic Pool Netting ("EPN") Rules of MBSD ("EPN Rules") in order to provide that EPN Users, as defined therein, are bound by proposed Rule 17B (Wind-down of the Corporation) and proposed Rule 40 (Market Disruption and Force Majeure) to be adopted to the MBSD Rules.⁸ Each of the proposed rules is referred to herein as a "Proposed Rule," and are collectively referred to as the "Proposed Rules."

The Proposed Rules are designed to (1) facilitate the implementation of the R&W Plan when necessary and, in particular, allow FICC to effectuate its strategy for winding down and transferring its business; (2) provide Members and Limited Members with transparency around critical provisions of the R&W Plan that relate to their rights, responsibilities and obligations; 9 and (3) provide FICC with the legal basis to implement those provisions of the R&W Plan when necessary, as described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of Amendment No. 1

This filing constitutes Amendment No. 1 ("Amendment") to the Proposed Rule Change (also referred to below as the "Original Filing") previously filed

by FICC.¹⁰ FICC is amending the proposed R&W Plan and the Original Filing in order to clarify certain matters and make minor technical and conforming changes to the R&W Plan, as described below and as marked on Exhibit 4 hereto. To the extent such changes to the Plan require changes to the Original Filing, the information provided under "Description of Proposed Changes'' in the Original Filing has been amended and is restated in its entirety below. Other sections of the Original Filing are unchanged and are restated in their entity for convenience.

First, this Amendment would clarify the meaning of the terms "cease to act," "Member default," "Defaulting Member," and "Member Default Losses" as such terms are used in the Plan. This Amendment would also make conforming changes as necessary to reflect the uses of these terms.

Second, this Amendment would clarify that actions and tools described in the Plan that are available in one phase of the Crisis Continuum may be used in subsequent phases of the Crisis Continuum when appropriate to address the applicable situation. This Amendment would also clarify that the allocation of losses resulting from a Member default would be applied when provided for, and in accordance with, Rule 4 of the GSD Rules and the MBSD Rules, as applicable.

Third, this Amendment would clarify that the Recovery Corridor (as defined therein) is not a "sub-phase" of the recovery phase. Rather, the Recovery Corridor is a period of time that would occur toward the end of the Member default phase, when indicators are that FICC may transition into the recovery phase. Thus, the Recovery Corridor precedes the recovery phase within the Crisis Continuum.

Fourth, this Amendment would make revisions to address the allocation of losses resulting from a Member default in order to more closely conform such statements to the changes proposed by the Loss Allocation Filing, as defined below.

Fifth, this Amendment would clarify the notifications that FICC would be required to make under the proposed GSD Rule 50 and MBSD Rule 40 (Market Disruption and Force Majeure).

Finally, this Amendment would make minor, technical and conforming revisions to correct typographical errors and to simplify descriptions. For example, such revisions would use

⁵ Securities Exchange Act Release No. 83509 (June 25, 2018), 83 FR 30785 (June 29, 2018) (SR– DTC–2017–021; SR–FICC–2017–021; SR–NSCC– 2017–017)

⁶To promote the public availability and transparency of its post-notice amendment, FICC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the Commission's website at https://www.sec.gov/rules/sro/ficc.htm and thus been publicly available since June 29, 2018.

⁷¹⁷ CFR 240.17Ad-22(e)(3)(ii)

^{*}The GSD Rules and the MBSD Rules are referred to collectively herein as the "Rules." Capitalized terms not defined herein are defined in the Rules. The Rules and the EPN Rules are available at http://www.dtcc.com/legal/rules-and-procedures.

⁹References herein to "Members" refer to GSD Netting Members and MBSD Clearing Members. References herein to "Limited Members" refer to participants of GSD or MBSD other than GSD Netting Members and MBSD Clearing Members, including, for example, GSD Comparison-Only Members, GSD Sponsored Members, GSD CCIT Members, and MBSD EPN Users.

¹⁰ See Securities Exchange Act Release No. 82580 (January 24, 2018), 83 FR 4341 (January 30, 2018) (SR-FICC-2017-805).

lower case for terms that are not defined therein, and would use upper case for terms that are defined. The Amendment would also simplify certain descriptions by removing extraneous words and statements that are repetitive. These minor, technical revisions would not alter the substance of the proposal.

Description of Proposed Changes

FICC is proposing to adopt the R&W Plan to be used by the Board and management of FICC in the event FICC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would identify (i) the recovery tools available to FICC to address the risks of (a) uncovered losses or liquidity shortfalls resulting from the default of one or more Members, and (b) losses arising from non-default events, such as damage to its physical assets, a cyber-attack, or custody and investment losses, and (ii) the strategy for implementation of such tools. The R&W Plan would also establish the strategy and framework for the orderly wind-down of FICC and the transfer of its business in the remote event the implementation of the available recovery tools does not successfully return FICC to financial viability.

As discussed in greater detail below, the R&W Plan would provide, among other matters, (i) an overview of the business of FICC and its parent, The Depository Trust & Clearing Corporation ("DTCC"); (ii) an analysis of FICC's intercompany arrangements and an existing link to another financial market infrastructures ("FMIs"); (iii) a description of FICC's services, and the criteria used to determine which services are considered critical; (iv) a description of the FICC and DTCC governance structure; (v) a description of the governance around the overall recovery and wind-down program; (vi) a discussion of tools available to FICC to mitigate credit/market and liquidity risks, including recovery indicators and triggers, and the governance around management of a stress event along a "Crisis Continuum" timeline; (vii) a discussion of potential non-default losses and the resources available to FICC to address such losses, including recovery triggers and tools to mitigate such losses; (viii) an analysis of the recovery tools' characteristics, including how they are comprehensive, effective, and transparent, how the tools provide appropriate incentives to Members to, among other things, control and monitor the risks they may present to FICC, and how FICC seeks to minimize the negative consequences of executing its

recovery tools; and (ix) the framework and approach for the orderly winddown and transfer of FICC's business, including an estimate of the time and costs to effect a recovery or orderly wind-down of FICC.

The R&W Plan would be structured as a roadmap, and would identify and describe the tools that FICC may use to effect a recovery from the events and scenarios described therein. Certain recovery tools that would be identified in the R&W Plan are based in the Rules (including the Proposed Rules) and, as such, descriptions of those tools would include descriptions of, and reference to, the applicable Rules and any related internal policies and procedures. Other recovery tools that would be identified in the R&W Plan are based in contractual arrangements to which FICC is a party, including, for example, existing committed or pre-arranged liquidity arrangements. Further, the R&W Plan would state that FICC may develop further supporting internal guidelines and materials that may provide operationally for matters described in the Plan, and that such documents would be supplemental and subordinate to the Plan.

Key factors considered in developing the R&W Plan and the types of tools available to FICC were its governance structure and the nature of the markets within which FICC operates. As a result of these considerations, many of the tools available to FICC that would be described in the R&W Plan are FICC's existing, business-as-usual risk management and Member default management tools, which would continue to be applied in scenarios of increasing stress. In addition to these existing, business-as-usual tools, the R&W Plan would describe FICC's other principal recovery tools, which include, for example, (i) identifying, monitoring and managing general business risk and holding sufficient liquid net assets funded by equity ("LNA") to cover potential general business losses pursuant to the Clearing Agency Policy on Capital Requirements ("Capital Policy"),¹¹ (ii) maintaining the Clearing Agency Capital Replenishment Plan ("Replenishment Plan") as a viable plan for the replenishment of capital should FICC's equity fall close to or below the amount being held pursuant to the Capital Policy, 12 and (iii) the process for the allocation of losses among Members, as provided in Rule 4 of the GSD Rules

and Rule 4 of the MBSD Rules. ¹³ The R&W Plan would provide governance around the selection and implementation of the recovery tool or tools most relevant to mitigate a stress scenario and any applicable loss or liquidity shortfall.

The development of the R&W Plan is facilitated by the Office of Recovery & Resolution Planning ("R&R Team") of DTCC.14 The R&R Team reports to the DTCC Management Committee ("Management Committee") and is responsible for maintaining the R&W Plan and for the development and ongoing maintenance of the overall recovery and wind-down planning process. The Board, or such committees as may be delegated authority by the Board from time to time pursuant to its charter, would review and approve the R&W Plan biennially, and would also review and approve any changes that are proposed to the R&W Plan outside of the biennial review.

As discussed in greater detail below, the Proposed Rules would define the procedures that may be employed in the event of FICC's wind-down and would provide for FICC's authority to take certain actions on the occurrence of a "Market Disruption Event," as defined therein. Significantly, the Proposed Rules would provide Members and Limited Members with transparency and certainty with respect to these matters. The Proposed Rules would facilitate the implementation of the R&W Plan, particularly FICC's strategy for winding down and transferring its business, and would provide FICC with the legal basis to implement those aspects of the R&W Plan.

¹¹ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR–DTC–2017–003, SR–FICC–2017–007, SR–NSCC–2017–004).

¹² See id.

 $^{^{\}rm 13}\,See$ GSD Rule 4 (Clearing Fund and Loss Allocation) and MBSD Rule 4 (Clearing Fund and Loss Allocation), supra note 8. FICC is proposing changes to Rule 4 regarding allocation of losses in a separate filing submitted simultaneously with the Original Filing. See Securities Exchange Act Release Nos. 82431 (January 2, 2018), 83 FR 871 (January 8, 2018) (SR-FICC-2017-021) and 82580 (January 24, 2018), 83 FR 4341 (January 30, 2018) (SR-FICC-2017-805) (collectively referred to herein as the "Loss Allocation Filing"). FICC has submitted an amendment to the Loss Allocation Filing. A copy of the amendment to the Loss Allocation Filing is available at http:// www.dtcc.com/legal/sec-rule-filings.aspx. FICC expects the Commission to review both proposals, as amended, together, and, as such, the proposal described in this filing anticipates the approval and implementation of those proposed changes to the

¹⁴ DTCC operates on a shared services model with respect to FICC and its other subsidiaries. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides a relevant service to a subsidiary, including FICC.

FICC R&W Plan

The R&W Plan is intended to be used by the Board and FICC's management in the event FICC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be structured to provide a roadmap, define the strategy, and identify the tools available to FICC to either (i) recover in the event it experiences losses that exceed its prefunded resources (such strategies and tools referred to herein as the "Recovery Plan") or (ii) wind-down its business in a manner designed to permit the continuation of its critical services in the event that such recovery efforts are not successful (such strategies and tools referred to herein as the "Winddown Plan"). The description of the R&W Plan below is intended to highlight the purpose and expected effects of the material aspects of the R&W Plan, and to provide Members and Limited Members with appropriate transparency into these features.

Business Overview, Critical Services, and Governance

The introduction to the R&W Plan would identify the document's purpose and its regulatory background, and would outline a summary of the Plan. The stated purpose of the R&W Plan is that it is to be used by the Board and FICC management in the event FICC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be maintained by FICC in compliance with Rule 17Ad–22(e)(3)(ii) under the Act ¹⁵ by providing plans for the recovery and orderly wind-down of FICC.

The R&W Plan would describe DTCC's business profile, provide a summary of the services of FICC as offered by each of the Divisions, and identify the intercompany arrangements and links between FICC and other entities, most notably a link between GSD and Chicago Mercantile Exchange Inc. ("CME"), which is also an FMI. This overview section would provide a context for the R&W Plan by describing FICC's business, organizational structure and critical links to other entities. By providing this context, this section would facilitate the analysis of the potential impact of utilizing the recovery tools set forth in later sections of the Recovery Plan, and the analysis of the factors that would be addressed in implementing the Wind-down Plan.

The Plan would provide a description of the critical contractual and operational arrangements between FICC and other legal entities, including the cross-margining agreement between GSD and CME, which is also an FMI.¹⁶ Pursuant to this arrangement, GSD offsets each cross-margining participant's residual margin amount (based on related positions) at GSD against the offsetting residual margin amounts of the participant (or its affiliate) at CME. GSD and CME may then reduce the amount of collateral that they collect to reflect the offsets between the cross-margining participant's positions at GSD and its (or its affiliate's) positions at CME. This section of the Plan, identifying and briefly describing FICC's established links, would provide a mapping of critical connections and dependencies that may need to be relied on or otherwise addressed in connection with the implementation of either the Recovery Plan or the Wind-down Plan.

The Plan would define the criteria for classifying certain of FICC's services as "critical," and would identify those critical services and the rationale for their classification. This section would provide an analysis of the potential systemic impact from a service disruption, and is important for evaluating how the recovery tools and the wind-down strategy would facilitate and provide for the continuation of FICC's critical services to the markets it serves. The criteria that would be used to identify an FICC service or function as critical would include consideration as to (1) whether there is a lack of alternative providers or products; (2) whether failure of the service could impact FICC's ability to perform its central counterparty services through either Division; (3) whether failure of the service could impact FICC's ability to perform its multilateral netting services through either Division and, as

such, could impact the volume of transactions; (4) whether failure of the service could impact FICC's ability to perform its book-entry delivery and settlement services through either Division and, as such, could impact transaction costs; (5) whether failure of the service could impact FICC's ability to perform its cash payment processing services through either Division and, as such, could impact the flow of liquidity in the U.S. financial markets; and (6) whether the service is interconnected with other participants and processes within the U.S. financial system, for example, with other FMIs, settlement banks, and broker-dealers. The Plan would then list each of those services, functions or activities that FICC has identified as "critical" based on the applicability of these six criteria. GSD's critical services would include, for example, its Real-Time Trade Matching ("RTTM®") service. 17 its services related to netting and settlement of submitted trades for Netting Members, 18 the Auction Takedown service,19 and the Repurchase Agreement Netting Service.²⁰ MBSD's critical services would include, for example, its RTTM® service,²¹ its netting service for to-beannounced ("TBA") transactions,22 its Electronic Pool Notification service,23 and its pool netting and settlement.24 The R&W Plan would also include a non-exhaustive list of FICC services that are not deemed critical.

The evaluation of which services provided by FICC are deemed critical is important for purposes of determining how the R&W Plan would facilitate the continuity of those services. As discussed further below, while FICC's Wind-down Plan would provide for the transfer of all critical services to a transferee in the event FICC's wind-down is implemented, it would anticipate that any non-critical services

DTCC is a user-owned and user-governed holding company and is the parent company of FICC and its affiliates, The Depository Trust Company ("DTC") and National Securities Clearing Corporation ("NSCC", and, together with FICC and DTC, the "Clearing Agencies"). The Plan would describe how corporate support services are provided to FICC from DTCC and DTCC's other subsidiaries through intercompany agreements under a shared services model.

¹⁶ Available at http://www.dtcc.com/~/media/ Files/Downloads/legal/rules/ficc_cme_crossmargin_ agreement.pdf. See also GSD Rule 43 (Cross-Margining Arrangements), supra note 8.

¹⁷ See GSD Rule 5 (Comparison System), GSD Rule 6A (Bilateral Comparison), GSD Rule 6B (Demand Comparison), and GSD Rule 6C (Locked-In Comparison), supra note 8.

¹⁸ See GSD Rule 11 (Netting System), GSD Rule 12 (Securities Settlement), and GSD Rule 13 (Funds-Only Settlement), supra note 8.

 $^{^{19}}$ See GSD Rule 6C (Locked-In Comparison) and GSD Rule 17 (Netting and Settlement of Netting-Eligible Auction Purchases), supra note 8.

²⁰ See GSD Rule 7 (Repo Transactions), GSD Rule 11 (Netting System), GSD Rule 18 (Special Provisions for Repo Transactions), GSD Rule 19 (Special Provisions for Brokered Repo Transactions), and GSD Rule 20 (Special Provisions for GCF Repo Transactions), supra note 8.

²¹ See MBSD Rule 5 (Trade Comparison), supra

²² See MBSD Rule 6 (TBA Netting), supra note 8.

²³ See EPN Rules, supra note 8.

²⁴ See MBSD Rule 8 (Pool Netting System) and MBSD Rule 9 (Pool Settlement with the Corporation), supra note 8.

^{15 17} CFR 240.17Ad-22(e)(3)(ii).

that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership, would also be transferred.

The Plan would describe the governance structure of both DTCC and FICC. This section of the Plan would identify the ownership and governance model of these entities at both the Board of Directors and management levels. The Plan would state that the stages of escalation required to manage recovery under the Recovery Plan or to invoke FICC's wind-down under the Winddown Plan would range from relevant business line managers up to the Board through FICC's governance structure. The Plan would then identify the parties responsible for certain activities under both the Recovery Plan and the Winddown Plan, and would describe their respective roles. The Plan would identify the Risk Committee of the Board ("Board Risk Committee") as being responsible for oversight of risk management activities at FICC, which include focusing on both oversight of risk management systems and processes designed to identify and manage various risks faced by FICC, and, due to FICC's critical role in the markets in which it operates, oversight of FICC's efforts to mitigate systemic risks that could impact those markets and the broader financial system.²⁵ The Plan would identify the DTCC Management Risk Committee ("Management Risk Committee") as primarily responsible for general, day-to-day risk management through delegated authority from the Board Risk Committee. The Plan would state that the Management Risk Committee has delegated specific dayto-day risk management, including management of risks addressed through margining systems and related activities, to the DTCC Group Chief Risk Office ("GCRO"), which works with staff within the DTCC Financial Risk Management group, Finally, the Plan would describe the role of the Management Committee, which provides overall direction for all aspects of FICC's business, technology, and operations and the functional areas that support these activities.

The Plan would describe the governance of recovery efforts in response to both default losses and non-default losses under the Recovery Plan, identifying the groups responsible for those recovery efforts. Specifically, the Plan would state that the Management

Risk Committee provides oversight of actions relating to the default of a Member, which would be reported and escalated to it through the GCRO, and the Management Committee provides oversight of actions relating to nondefault events that could result in a loss, which would be reported and escalated to it from the DTCC Chief Financial Officer ("CFO") and the DTCC Treasury group that reports to the CFO, and from other relevant subject matter experts based on the nature and circumstances of the non-default event.26 More generally, the Plan would state that the type of loss and the nature and circumstances of the events that lead to the loss would dictate the components of governance to address that loss, including the escalation path to authorize those actions. As described further below, both the Recovery Plan and the Wind-down Plan would describe the governance of escalations, decisions, and actions under each of those plans.

Finally, the Plan would describe the role of the R&R Team in managing the overall recovery and wind-down program and plans for each of the Clearing Agencies.

FICC Recovery Plan

The Recovery Plan is intended to be a roadmap of those actions that FICC may employ across both Divisions to monitor and, as needed, stabilize its financial condition. As each event that could lead to a financial loss could be unique in its circumstances, the Recovery Plan would not be prescriptive and would permit FICC to maintain flexibility in its use of identified tools and in the sequence in which such tools are used, subject to any conditions in the Rules or the contractual arrangement on which such tool is based. FICC's Recovery Plan would consist of (1) a description of the risk management surveillance, tools, and governance that FICC would employ across evolving stress scenarios that it may face as it transitions through a "Crisis Continuum," described below; (2) a description of FICC's risk of losses that may result from non-default events, and the financial resources and recovery

tools available to FICC to manage those risks and any resulting losses; and (3) an evaluation of the characteristics of the recovery tools that may be used in response to either default losses or non-default losses, as described in greater detail below. In all cases, FICC would act in accordance with the Rules, within the governance structure described in the R&W Plan, and in accordance with applicable regulatory oversight to address each situation in order to best protect FICC, the Members, and the markets in which it operates.

Managing Member Default Losses and Liquidity Needs Through the Crisis Continuum. The Recovery Plan would describe the risk management surveillance, tools, and governance that FICC may employ across an increasing stress environment, which is referred to as the "Crisis Continuum." This description would identify those tools that can be employed to mitigate losses, and mitigate or minimize liquidity needs, as the market environment becomes increasingly stressed. The phases of the Crisis Continuum would include (1) a stable market phase, (2) a stress market phase, (3) a phase commencing with FICC's decision to cease to act for a Member or Affiliated Family of Members (referred to in the Plan as the "Member default phase"),27 and (4) a recovery phase. This section of the Recovery Plan would address conditions and circumstances relating to FICC's decision to cease to act for a Member pursuant to the applicable Rules.²⁸ In the Plan, the term "cease to act" and the actions that lead to such decision are used within the context of each Division's Rules, in particular Rules 21 and 22 of the GSD Rules and Rules 14 and 16 of the MBSD Rules.²⁹ Further, for ease of reference, the R&W Plan would, for purposes of the Plan, use the term "Member default" to refer to the event or events that precipitate FICC ceasing to act for a Member or an Affiliated Family, would use the term "Defaulting Member" to refer to a Member for which NSCC has ceased to act, and would use the term "Member Default Losses" to refer to losses that arise out of or relate to the Member default (including any losses that arise from liquidation of that Member's portfolio), and to distinguish such losses

²⁵ The charter of the Board Risk Committee is available at http://www.dtcc.com/~/media/Files/Downloads/legal/policy-and-compliance/DTCC-BOD-Risk-Committee-Charter.pdf.

²⁶ The Plan would state that these groups would be involved to address how to mitigate the financial impact of non-default losses, and in recommending mitigating actions, the Management Committee would consider information and recommendations from relevant subject matter experts based on the nature and circumstances of the non-default event. Any necessary operational response to these events, however, would be managed in accordance with applicable incident response/business continuity process; for example, processes established by the DTCC Technology Risk Management group would be followed in response to a cyber event.

²⁷ The Plan would define an "Affiliated Family" of Members as a number of affiliated entities that are all Members of either GSD or MBSD.

²⁸ See GSD Rule 21 (Restrictions on Access to Services) and MBSD Rule 14 (Restrictions on Access to Services), supra note 8.

²⁹ See GSD Rules 21 (Restrictions on Access to Services) and 22 (Insolvency of a Member), and MBSD Rules 14 (Restrictions on Access to Services) and 16 (Insolvency of a Member), *supra* note 8.

from those that arise out of the business or other events not related to a Member default, which are separately addressed in the Plan.

The Recovery Plan would provide context to its roadmap through this Crisis Continuum by describing FICC's ongoing management of credit, market and liquidity risk across the Divisions, and its existing process for measuring and reporting its risks as they align with established thresholds for its tolerance of those risks. The Recovery Plan would discuss the management of credit/ market risk and liquidity exposures together, because the tools that address these risks can be deployed either separately or in a coordinated approach in order to address both exposures. FICC manages these risk exposures collectively to limit their overall impact on FICC and the memberships of the Divisions. As part of its market risk management strategy, FICC manages its credit exposure to Members by determining the appropriate required deposits to the GSD and MBSD Clearing Fund and monitoring its sufficiency, as provided for in the applicable Rules.³⁰ FICC manages its liquidity risks with an objective of maintaining sufficient resources to be able to fulfill obligations that have been guaranteed by FICC in the event of a Member default that presents the largest aggregate liquidity exposure to FICC over the settlement cycle.31

The Recovery Plan would outline the metrics and indicators that FICC has developed to evaluate a stress situation against established risk tolerance thresholds. Each risk mitigation tool identified in the Recovery Plan would include a description of the escalation

thresholds that allow for effective and timely reporting to the appropriate internal management staff and committees, or to the Board. The Recovery Plan would make clear that these tools and escalation protocols would be calibrated across each phase of the Crisis Continuum. The Recovery Plan would also establish that FICC would retain the flexibility to deploy such tools either separately or in a coordinated approach, and to use other alternatives to these actions and tools as necessitated by the circumstances of a particular Member default in accordance with the applicable Rules. Therefore, the Recovery Plan would both provide FICC with a roadmap to follow within each phase of the Crisis Continuum, and would permit it to adjust its risk management measures to address the unique circumstances of each event.

The Recovery Plan would describe the conditions that mark each phase of the Crisis Continuum, and would identify actions that FICC could take as it transitions through each phase in order to both prevent losses from materializing through active risk management, and to restore the financial health of FICC during a period of stress

The stable market phase of the Crisis Continuum would describe active risk management activities in the normal course of business. These activities would include (1) routine monitoring of margin adequacy through daily review of back testing and stress testing results that review the adequacy of the margin calculations for each of GSD and MBSD, and escalation of those results to internal and Board committees; 32 and (2) routine monitoring of liquidity adequacy through review of daily liquidity studies that measure sufficiency of available liquidity resources to meet cash settlement obligations of the Member that would generate the largest aggregate payment obligation.33

The Recovery Plan would describe some of the indicators of the stress market phase of the Crisis Continuum, which would include, for example, volatility in market prices of certain assets where there is increased uncertainty among market participants about the fundamental value of those assets. This phase would involve general market stresses, when no Member default would be imminent. Within the description of this phase, the Recovery Plan would provide that FICC may take targeted, routine risk management measures as necessary and as permitted by the Rules.

Within the Member default phase of the Crisis Continuum, the Recovery Plan would provide a roadmap for the existing procedures that FICC would follow in the event of a Member default and any decision by FICC to cease to act for that Member.³⁴ The Recovery Plan would provide that the objectives of FICC's actions upon a Member or Affiliated Family default are to (1) minimize losses and market exposure of the affected Members and the applicable Division's non-Defaulting Members; and (2), to the extent practicable, minimize disturbances to the affected markets. The Recovery Plan would describe tools, actions, and related governance for both market risk monitoring and liquidity risk monitoring through this phase. For example, in connection with managing its market risk during this phase, FICC would, pursuant to the applicable Division's Rules, (1) monitor and assess the adequacy of the GSD and MBSD Clearing Fund resources; (2), when necessary and appropriate pursuant to the applicable Division's Rules, assess and collect additional margin requirements; and (3) follow its operational procedures to liquidate the Defaulting Member's portfolio. Management of liquidity risk through this phase would involve ongoing monitoring of the adequacy of FICC's liquidity resources, and the Recovery Plan would identify certain actions FICC may deploy as it deems necessary to mitigate a potential liquidity shortfall, which would include, for example, adjusting its strategy for closing out the Defaulting Member's portfolio or seeking additional liquidity resources. The Recovery Plan would state that, throughout this phase, relevant information would be escalated and reported to both internal management committees and the Board Risk Committee.

The Recovery Plan would also identify financial resources available to FICC, pursuant to the Rules, to address losses arising out of a Member default. Specifically, GSD Rule 4 and MBSD Rule 4, as each are proposed to be amended by the Loss Allocation Filing,

 $^{^{30}\,}See$ GSD Rule 4 (Clearing Fund and Loss Allocation) and MBSD Rule 4 (Clearing Fund and Loss Allocation), supra note 13. Because GSD and MBSD do not maintain a guaranty fund separate and apart from the Clearing Fund they collect from Members, FICC monitors its credit exposure to its Members by managing the market risks of each Member's unsettled portfolio through the collection of each Division's Clearing Fund. The aggregate of all Members' Required Clearing Fund deposits to each of GSD or MBSD comprises that Division's Clearing Fund that represents FICC's prefunded resources to address uncovered loss exposures as provided in each Division's proposed Rule 4. Therefore, FICC's market risk management strategy for both Divisions is designed to comply with Rule 17Ad-22(e)(4) under the Act, where these risks are referred to as "credit risks." See also 17 CFR 240.17Ad-22(e)(4).

³¹ FICC's liquidity risk management strategy, including the manner in which FICC utilizes its liquidity tools, is described in the Clearing Agency Liquidity Risk Management Framework. See Securities Exchange Act Release Nos. 80489 (April 19, 2017), 82 FR 19120 (April 25, 2017) (SR–DTC–2017–004, SR–NSCC–2017–005, SR–FICC–2017–008); 81194 (July 24, 2017), 82 FR 35241 (July 28, 2017) (SR–DTC–2017–004, SR–NSCC–2017–005, SR–FICC–2017–008).

³² FICC's stress testing practices are described in the Clearing Agency Stress Testing Framework (Market Risk). See Securities Exchange Act Release Nos. 80485 (April 19, 2017), 82 FR 19131 (April 25, 2017) (SR–DTC–2017–005, SR–FICC–2017–009, SR–NSCC–2017–006; 81192 (July 24, 2017), 82 FR 35245 (July 28, 2017) (SR–DTC–2017–005, SR–FICC–2017–009, SR–NSCC–2017–006).

³³ See supra note 31.

³⁴ See GSD Rule 21 (Restrictions on Access to Services), GSD Rule 22A (Procedures for When the Corporation Ceases to Act), MBSD Rule 14 (Restrictions on Access to Services), and MBSD Rule 17 (Procedures for When the Corporation Ceases to Act), supra note 8.

would provide that losses remaining after application of the Defaulting Member's resources be satisfied first by applying a "Corporate Contribution," and then, if necessary, by allocating remaining losses among the membership in accordance with such GSD Rule 4 and MBSD Rule 4, as applicable.³⁵

In order to provide for an effective and timely recovery, the Recovery Plan would describe the period of time that would occur near the end of the Member default phase, during which FICC may experience stress events or observe early warning indicators that allow it to evaluate its options and prepare for the recovery phase (referred to in the Plan as the "Recovery Corridor"). The Recovery Plan would then describe the recovery phase of the Crisis Continuum, which would begin on the date that FICC issues the first Loss Allocation Notice of the second loss allocation round with respect to a given "Event Period." 36 The recovery phase would describe actions that FICC may take to avoid entering into a winddown of its business.

FICC expects that significant deterioration of liquidity resources would cause it to enter the Recovery Corridor. As such, the Plan would describe the actions FICC may take at this stage aimed at replenishing those resources. Recovery Corridor indicators may include, for example, a rapid and material change in market prices or substantial intraday activity volume by

the Member that subsequently defaults, neither of which are mitigated by intraday margin calls, or subsequent defaults by other Members or Affiliated Families during a compressed time period. Throughout the Recovery Corridor, FICC would monitor the adequacy of the Divisions' respective resources and the expected timing of replenishment of those resources, and would do so through the monitoring of certain corridor indicator metrics.

The majority of the corridor indicators, as identified in the Recovery Plan, relate directly to conditions that may require either Division to adjust its strategy for hedging and liquidating a Defaulting Member's portfolio, and any such changes would include an assessment of the status of the corridor indicators. Corridor indicators would include, for example, effectiveness and speed of FICC's efforts to close out the portfolio of the Defaulting Member, and an impediment to the availability of its financial resources. For each corridor indicator, the Recovery Plan would identify (1) measures of the indicator, (2) evaluations of the status of the indicator, (3) metrics for determining the status of the deterioration or improvement of the indicator, and (4) "Corridor Actions," which are steps that may be taken to improve the status of the indicator,37 as well as management escalations required to authorize those steps. Because FICC has never experienced the default of multiple Members, it has not, historically, measured the deterioration or improvements metrics of the corridor indicators. As such, these metrics were chosen based on the business judgment of FICC management.

The Recovery Plan would also describe the reporting and escalation of the status of the corridor indicators throughout the Recovery Corridor. Significant deterioration of a corridor indicator, as measured by the metrics set out in the Recovery Plan, would be escalated to the Board. FICC management would review the corridor indicators and the related metrics at least annually, and would modify these metrics as necessary in light of observations from simulations of Member defaults and other analyses. Any proposed modifications would be reviewed by the Management Risk Committee and the Board Risk

Committee. The Recovery Plan would estimate that FICC may remain in the Recovery Corridor between one day and two weeks. This estimate is based on historical data observed in past Member defaults, the results of simulations of Member defaults, and periodic liquidity analyses conducted by FICC. The actual length of a Recovery Corridor would vary based on actual market conditions observed at the time, and FICC would expect the Recovery Corridor to be shorter in market conditions of increased stress.

The Recovery Plan would outline steps by which FICC may allocate its losses, which would occur when and in the order provided in the amended GSD Rule 4 and MBSD Rule 4, as applicable.38 The Recovery Plan would also identify tools that may be used to address foreseeable shortfalls of FICC's liquidity resources following a Member default, and would provide that these tools may be used as appropriate during the Crisis Continuum to address liquidity shortfalls if they arise. The goal in managing FICC's qualified liquidity resources is to maximize resource availability in an evolving stress situation, to maintain flexibility in the order and use of sources of liquidity, and to repay any third party lenders of liquidity in a timely manner. Additional voluntary or uncommitted tools to address potential liquidity shortfalls, for example uncommitted bank loans, which may supplement FICC's other liquid resources described herein, would also be identified in the Recovery Plan. The Recovery Plan would state that, due to the extreme nature of a stress event that would cause FICC to consider the use of these liquidity tools, the availability and capacity of these liquidity tools, and the willingness of counterparties to lend, cannot be accurately predicted and are dependent on the circumstances of the applicable stress period, including market price volatility, actual or perceived disruptions in financial markets, the costs to FICC of utilizing these tools, and any potential impact on FICC's credit rating.

As stated above, the Recovery Plan

As stated above, the Recovery Plan would state that FICC will have entered the recovery phase on the date that it issues the first Loss Allocation Notice of the second loss allocation round with respect to a given Event Period. The Recovery Plan would provide that, during the recovery phase, FICC would

³⁵ See supra note 13. The Loss Allocation Filing proposes to amend GSD Rule 4 and MBSD Rule 4 to define the amount FICC would contribute to address a loss resulting from either a Member default or a non-default event as the "Corporate Contribution." This amount would be 50 percent (50%) of the "General Business Risk Capital Requirement," which is calculated pursuant to the Capital Policy and is an amount sufficient to cover potential general business losses so that FICC can continue operations and services as a going concern if those losses materialize, in compliance with Rule 17Ad–22(e)(15) under the Act. See also supra note 11; 17 CFR 240.17Ad–22(e)(15).

 $^{^{36}\,\}mathrm{The}\;\mathrm{Loss}\;\mathrm{Allocation}\;\mathrm{Filing}\;\mathrm{proposes}\;\mathrm{to}\;\mathrm{amend}$ Rule 4 to introduce the concept of an "Event Period" as the ten (10) Business Days beginning on (i) with respect to a Member default, the day on which NSCC notifies Members that it has ceased to act for a Member under the Rules, or (ii) with respect to a non-default loss, the day that NSCC notifies Members of the determination by the Board that there is a non-default loss event, as described in greater detail in that filing. The proposed GSD Rule 4 and MBSD Rule 4 would define a "round" as a series of loss allocations relating to an Event Period, and would provide that the first Loss Allocation Notice in a first, second, or subsequent round shall expressly state that such notice reflects the beginning of a first, second, or subsequent round. The maximum allocable loss amount of a round is equal to the sum of the "Loss Allocation Caps" (as defined in the proposed GSD Rule 4 and MBSD Rule 4) of those Members included in the round. See supra note 13.

³⁷ The Corridor Actions that would be identified in the Plan are indicative, but not prescriptive; therefore, if FICC needs to consider alternative actions due to the applicable facts and circumstances, the escalation of those alternative actions would follow the same escalation protocol identified in the Plan for the Corridor Indicator to which the action relates.

³⁸ As these matters are described in greater detail in the Loss Allocation Filing and in the proposed amendments to GSD Rule 4 and MBSD Rule 4, described therein, reference is made to that filing and the details are not repeated here. *See supra* note 13.

continue and, as needed, enhance, the monitoring and remedial actions already described in connection with previous phases of the Crisis Continuum, and would remain in the recovery phase until its financial resources are expected to be or are fully replenished, or until the Wind-down Plan is triggered, as described below.

The Recovery Plan would describe governance for the actions and tools that may be employed within each phase of the Crisis Continuum, which would be dictated by the facts and circumstances applicable to the situation being addressed. Such facts and circumstances would be measured by the various indicators and metrics applicable to that phase of the Crisis Continuum, and would follow the relevant escalation protocol that would be described in the Recovery Plan. The Recovery Plan would also describe the governance procedures around a decision to cease to act for a Member, pursuant to the applicable Division's Rules, and around the management and oversight of the subsequent liquidation of the Defaulting Member's portfolio. The Recovery Plan would state that, overall, FICC would retain flexibility in accordance with each Division's Rules, its governance structure, and its regulatory oversight, to address a particular situation in order to best protect FICC and the Members, and to meet the primary objectives, throughout the Crisis Continuum, of minimizing losses and, where consistent and practicable, minimizing disturbance to affected markets.

Non-Default Losses. The Recovery Plan would outline how FICC may address losses that result from events other than a Member default. While these matters are addressed in greater detail in other documents, this section of the Plan would provide a roadmap to those documents and an outline for FICC's approach to monitoring and managing losses that could result from a non-default event. The Plan would first identify some of the risks FICC faces that could lead to these losses, which include, for example, the business and profit/loss risks of unexpected declines in revenue or growth of expenses; the operational risks of disruptions to systems or processes that could lead to large losses, including those resulting from, for example, a cyber-attack; and custody or investment risks that could lead to financial losses. The Recovery Plan would describe FICC's overall strategy for the management of these risks, which includes a "three lines of defense" approach to risk management that allows for comprehensive

management of risk across the organization.³⁹ The Recovery Plan would also describe FICC's approach to financial risk and capital management. The Plan would identify key aspects of this approach, including, for example, an annual budget process, business line performance reviews with management, and regular review of capital requirements against LNA. These risk management strategies are collectively intended to allow FICC to effectively identify, monitor, and manage risks of non-default losses.

The Plan would identify the two categories of financial resources FICC maintains to cover losses and expenses arising from non-default risks or events as (1) LNA, maintained, monitored, and managed pursuant to the Capital Policy, which include (a) amounts held in satisfaction of the General Business Risk Capital Requirement, 40 (b) the Corporate Contribution,⁴¹ and (c) other amounts held in excess of FICC's capital requirements pursuant to the Capital Policy; and (2) resources available pursuant to the loss allocation provisions of GSD Rule 4 and MBSD Rule 4.42

The Plan would address the process by which the CFO and the DTCC Treasury group would determine which available LNA resources are most appropriate to cover a loss that is caused by a non-default event. This determination involves an evaluation of a number of factors, including the current and expected size of the loss, the expected time horizon over when the loss or additional expenses would materialize, the current and projected available LNA, and the likelihood LNA could be successfully replenished

pursuant to the Replenishment Plan, if triggered. As Finally the Plan would discuss how FICC would apply its resources to address losses resulting from a non-default event, including the order of resources it would apply if the loss or liability exceeds FICC's excess LNA amounts, or is large relative thereto, and the Board has declared the event a "Declared Non-Default Loss Event" pursuant to GSD Rule 4 and MBSD Rule 4.44

The Plan would also describe proposed GSD Rule 50 (Market Disruption and Force Majeure) and proposed MBSD Rule 40 (Market Disruption and Force Majeure), which FICC is proposing to adopt in the GSD Rule and MBSD Rules, respectively. This Proposed Rule would provide transparency around how FICC would address extraordinary events that may occur outside its control. Specifically, the Proposed Rule would define a "Market Disruption Event" and the governance around a determination that such an event has occurred. The Proposed Rule would also describe FICC's authority to take actions during the pendency of a Market Disruption Event that it deems appropriate to address such an event and facilitate the continuation of its services, if practicable, as described in greater detail below.

The Plan would describe the interaction between the Proposed Rule and FICC's existing processes and procedures addressing business continuity management and disaster recovery (generally, the "BCM/DR procedures"), making clear that the Proposed Rule is designed to support those BCM/DR procedures and to address circumstances that may be exogenous to FICC and not necessarily addressed by the BCM/DR procedures. Finally, the Plan would describe that, because the operation of the Proposed Rule is specific to each applicable Market Disruption Event, the Proposed Rule does not define a time limit on its application. However, the Plan would note that actions authorized by the Proposed Rule would be limited to the pendency of the applicable Market Disruption Event, as made clear in the Proposed Rule. Overall, the Proposed Rule is designed to mitigate risks caused by Market Disruption Events and, thereby, minimize the risk of financial loss that may result from such events.

Recovery Tool Characteristics. The Recovery Plan would describe FICC's evaluation of the tools identified within the Recovery Plan, and its rationale for

³⁹ This "three lines of defense" approach to risk management includes (1) a first line of defense comprised of the various business lines and functional units that support the products and services offered by FICC; (2) a second line of defense comprised of control functions that support FICC, including the risk management, legal and compliance areas; and (3) a third line of defense, which is performed by an internal audit group. The Clearing Agency Risk Management Framework includes a description of this "three lines of defense" approach to risk management, and addresses how FICC comprehensively manages various risks, including operational, general business, investment, custody, and other risks that arise in or are borne by it. See Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR-DTC-2017-013, SR-FICC-2017-016, SR-NSCC-2017-012). The Clearing Agency Operational Risk Management Framework describes the manner in which FICC manages operational risks, as defined therein. See Securities Exchange Act Release No. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR-DTC-2017-014, SR-FICC-2017-017, SR-NSCC-2017-013).

⁴⁰ See supra note 35.

⁴¹ See supra note 35.

⁴² See supra note 13.

⁴³ See supra note 11.

⁴⁴ See supra note 13.

concluding that such tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to Members and minimize negative impact on Members and the financial system, in compliance with guidance published by the Commission in connection with the adoption of Rule 17Ad–22(e)(3)(ii) under the Act. ⁴⁵ FICC's analysis and the conclusions set forth in this section of the Recovery Plan are described in greater detail in Item 3(b) of this filing, below.

FICC Wind-Down Plan

The Wind-down Plan would provide the framework and strategy for the orderly wind-down of FICC if the use of the recovery tools described in the Recovery Plan do not successfully return FICC to financial viability. While FICC believes that, given the comprehensive nature of the recovery tools, such event is extremely unlikely, as described in greater detail below, FICC is proposing a wind-down strategy that provides for (1) the transfer of FICC's business, assets and memberships of both Divisions to another legal entity, (2) such transfer being effected in connection with proceedings under Chapter 11 of the U.S. Federal Bankruptcy Code, 46 and (3) after effectuating this transfer, FICC liquidating any remaining assets in an orderly manner in bankruptcy proceedings. FICC believes that the proposed transfer approach to a winddown would meet its objectives of (1) assuring that FICC's critical services will be available to the market as long as there are Members in good standing, and (2) minimizing disruption to the operations of Members and financial markets generally that might be caused by FICC's failure.

In describing the transfer approach to FICC's Wind-down Plan, the Plan would identify the factors that FICC considered in developing this approach, including the fact that FICC does not own material assets that are unrelated to its clearance and settlement activities. As such, a business reorganization or "bail-in" of debt approach would be unlikely to mitigate significant losses. Additionally, FICC's approach was developed in consideration of its critical and unique position in the U.S. markets, which precludes any approach that would cause FICC's critical services to no longer be available.

First, the Wind-down Plan would describe the potential scenarios that could lead to the wind-down of FICC, and the likelihood of such scenarios. The Wind-down Plan would identify the time period leading up to a decision to wind-down FICC as the "Runway Period." This period would follow the implementation of any recovery tools, as it may take a period of time, depending on the severity of the market stress at that time, for these tools to be effective or for FICC to realize a loss sufficient to cause it to be unable to effectuate settlements and repay its obligations.⁴⁷ The Wind-down Plan would identify some of the indicators that it has entered this Runway Period, which would include, for example, successive Member defaults, significant Member retirements thereafter, and FICC's inability to replenish its financial resources following the liquidation of the portfolio of the Defaulting Member(s).

The trigger for implementing the Wind-down Plan would be a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning FICC to viability as a going concern. As described in the Plan, FICC believes this is an appropriate trigger because it is both broad and flexible enough to cover a variety of scenarios, and would align incentives of FICC and the Members to avoid actions that might undermine FICC's recovery efforts. Additionally, this approach takes into account the characteristics of FICC's recovery tools and enables the Board to consider (1) the presence of indicators of a successful or unsuccessful recovery, and (2) potential for knock-on effects of continued iterative application of FICC's recovery tools.

The Wind-down Plan would describe the general objectives of the transfer strategy, and would address assumptions regarding the transfer of FICC's critical services, business, assets and membership, and the assignment of GSD's link with another FMI, to another legal entity that is legally, financially, and operationally able to provide FICC's critical services to entities that wish to continue their membership following the transfer ("Transferee"). The Winddown Plan would provide that the Transferee would be either (1) a third party legal entity, which may be an

existing or newly established legal entity or a bridge entity formed to operate the business on an interim basis to enable the business to be transferred subsequently ("Third Party Transferee"); or (2) an existing, debt-free failover legal entity established ex-ante by DTCC ("Failover Transferee") to be used as an alternative Transferee in the event that no viable or preferable Third Party Transferee timely commits to acquire FICC's business. FICC would seek to identify the proposed Transferee, and negotiate and enter into transfer arrangements during the Runway Period and prior to making any filings under Chapter 11 of the U.S. Federal Bankruptcy Code. 48 As stated above, the Wind-down Plan would anticipate that the transfer to the Transferee be effected in connection with proceedings under Chapter 11 of the U.S. Federal Bankruptcy Code, and pursuant to a bankruptcy court order under Section 363 of the Bankruptcy Code, such that the transfer would be free and clear of claims against, and interests in, FICC, except to the extent expressly provided in the court's order.49

In order to effect a timely transfer of its services and minimize the market and operational disruption of such transfer, FICC would expect to transfer all of its critical services and any noncritical services that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership. Following the transfer, the Wind-down Plan would anticipate that the Transferee and its continuing membership would determine whether to continue to provide any transferred non-critical service on an ongoing basis, or terminate the non-critical service following some transition period. FICC's Wind-down Plan would anticipate that the Transferee would enter into a transition services agreement with DTCC so that DTCC would continue to provide the shared services it currently provides to FICC, including staffing, infrastructure and operational support. The Wind-down Plan would also anticipate the assignment of FICC's link arrangements, including its arrangements with clearing banks and GSD's cross-margining arrangement with CME, described above, to the Transferee.50 The Wind-down Plan

⁴⁵ Standards for Covered Clearing Agencies, Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14).

^{46 11} U.S.C. 1101 et seq.

⁴⁷ The Wind-down Plan would state that, given FICC's position as a user-governed financial market utility, it is possible that Members might voluntarily elect to provide additional support during the recovery phase leading up to a potential trigger of the Wind-down Plan, but would also make clear that FICC cannot predict the willingness of Members to do so.

⁴⁸ See 11 U.S.C. et seq.

⁴⁹ See id. at 363.

⁵⁰ The proposed transfer arrangements outlined in the Wind-down Plan do not contemplate the transfer of any credit or funding agreements, which are generally not assignable by FICC. However, to the extent the Transferee adopts rules substantially Continued

would provide that Members' open positions existing prior to the effective time of the transfer would be addressed by the provisions of the proposed Winddown Rule, as defined and described below, and the existing GSD Rule 22B (Corporation Default) and MBSD Rule 17 (Corporation Default) (collectively, "Corporation Default Rule"), as applicable, and that the Transferee would not acquire any pending or open transactions with the transfer of the business.51 The Wind-down Plan would anticipate that the Transferee would accept transactions for processing with a trade date from and after the effective time of the transfer.

The Wind-down Plan would provide that, following the effectiveness of the transfer to the Transferee, the wind-down of FICC would involve addressing any residual claims against FICC through the bankruptcy process and liquidating the legal entity. As such, and as stated above, the Wind-down Plan does not contemplate FICC continuing to provide services in any capacity following the transfer time, and any services not transferred would be terminated.

The Wind-down Plan would also identify the key dependencies for the effectiveness of the transfer, which include regulatory approvals that would permit the Transferee to be legally qualified to provide the transferred services from and after the transfer, and approval by the applicable bankruptcy court of, among other things, the proposed sale, assignments, and transfers to the Transferee.

The Wind-down Plan would address governance matters related to the execution of the transfer of FICC's business and its wind-down. The Winddown Plan would address the duties of the Board to execute the wind-down of FICC in conformity with (1) the Rules, (2) the Board's fiduciary duties, which mandate that it exercise reasonable business judgment in performing these duties, and (3) FICC's regulatory obligations under the Act as a registered clearing agency. The Wind-down Plan would also identify certain factors the Board may consider in making these decisions, which would include, for example, whether FICC could safely stabilize the business and protect its

identical to those FICC has in effect prior to the transfer, it would have the benefit of any rules-based liquidity funding. The Wind-down Plan contemplates that neither of the Divisions' respective Clearing Funds would be transferred to the Transferee, as they are not held in a bankruptcy remote manner and they are the primary prefunded liquidity resource to be accessed in the recovery

value without seeking bankruptcy protection, and FICC's ability to continue to meet its regulatory requirements.

The Wind-down Plan would describe (1) actions FICC or DTCC may take to prepare for wind-down in the period before FICC experiences any financial distress, (2) actions FICC would take both during the recovery phase and the Runway Period to prepare for the execution of the Wind-down Plan, and (3) actions FICC would take upon commencement of bankruptcy proceedings to effectuate the Wind-down Plan.

Finally, the Wind-down Plan would include an analysis of the estimated time and costs to effectuate the plan, and would provide that this estimate be reviewed and approved by the Board annually. In order to estimate the length of time it might take to achieve a recovery or orderly wind-down of FICC's critical operations, as contemplated by the R&W Plan, the Wind-down Plan would include an analysis of the possible sequencing and length of time it might take to complete an orderly wind-down and transfer of critical operations, as described in earlier sections of the R&W Plan. The Wind-down Plan would also include in this analysis consideration of other factors, including the time it might take to complete any further attempts at recovery under the Recovery Plan. The Wind-down Plan would then multiply this estimated length of time by FICC's average monthly operating expenses, including adjustments to account for changes to FICC's profit and expense profile during these circumstances, over the previous twelve months to determine the amount of LNA that it should hold to achieve a recovery or orderly wind-down of FICC's critical operations. The estimated wind-down costs would constitute the "Recovery/ Wind-down Capital Requirement" under the Capital Policy.⁵² Under that policy, the General Business Risk Capital Requirement is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement.53

The R&W Plan is designed as a roadmap, and the types of actions that may be taken both leading up to and in connection with implementation of the Wind-down Plan would be primarily addressed in other supporting documentation referred to therein.

The Wind-down Plan would address proposed GSD Rule 22D and MBSD Rule 17B (Wind-down of the Corporation), which would be adopted to facilitate the implementation of the Wind-down Plan, and are discussed below.

Proposed Rules

In connection with the adoption of the R&W Plan, FICC is proposing to adopt the Proposed Rules, each described below. The Proposed Rules would facilitate the execution of the R&W Plan and would provide Members and Limited Members with transparency as to critical aspects of the Plan, particularly as they relate to the rights and responsibilities of both FICC and Members. The Proposed Rules also provide a legal basis to these aspects of the Plan.

GSD Rule 22D and MBSD Rule 17B (Wind-Down of the Corporation)

The proposed GSD Rule 22D and MBSD Rule 17B (collectively, "Winddown Rule") would be adopted by both Divisions to facilitate the execution of the Wind-down Plan. The Wind-down Rule would include a proposed set of defined terms that would be applicable only to the provisions of this Proposed Rule. The Wind-down Rule would make clear that a wind-down of FICC's business would occur (1) after a decision is made by the Board, and (2) in connection with the transfer of FICC's services to a Transferee, as described therein. Because GSD and MBSD are both divisions of FICC, the individual Wind-down Rules are designed to work together. A decision by the Board to initiate the Wind-down Plan would be pursuant to, and trigger the provisions of, the Wind-down Rule of each Division simultaneously. Generally, the proposed Wind-down Rule is designed to create clear mechanisms for the transfer of Eligible Members, Eligible Limited Members, and Settling Banks (as these terms would be defined in the Wind-down Rule), and FICC's business in order to provide for continued access to critical services and to minimize disruption to the markets in the event the Wind-down Plan is initiated.

Wind-down Trigger. First, the Proposed Rule would make clear that the Board is responsible for initiating the Wind-down Plan, and would identify the criteria the Board would consider when making this determination. As provided for in the Wind-down Plan and in the proposed Wind-down Rule, the Board would initiate the Plan if, in the exercise of its business judgment and subject to its fiduciary duties, it has determined that the execution of the Recovery Plan has not or is not likely to restore FICC to viability as a going concern, and the

⁵¹ See supra note 8.

⁵² See supra note 11.

⁵³ See supra note 11.

implementation of the Wind-down Plan, including the transfer of FICC's business, is in the best interests of FICC, Members and Limited Members of both Divisions, its shareholders and creditors, and the U.S. financial markets.

Identification of Critical Services; Designation of Dates and Times for Specific Actions. The Proposed Rule would provide that, upon making a determination to initiate the Winddown Plan, the Board would identify the critical and non-critical services that would be transferred to the Transferee at the Transfer Time (as defined below and in the Proposed Rule), as well as any non-critical services that would not be transferred to the Transferee. The proposed Wind-down Rule would establish that any services transferred to the Transferee will only be provided by the Transferee as of the Transfer Time, and that any non-critical services that are not transferred to the Transferee would be terminated at the Transfer Time. The Proposed Rule would also provide that the Board would establish (1) an effective time for the transfer of FICC's business to a Transferee ("Transfer Time"), (2) the last day that transactions may be submitted to either Division for processing ("Last Transaction Acceptance Date"), and (3) the last day that transactions submitted to either Division will be settled ("Last Settlement Date").

Treatment of Pending Transactions. The Wind-down Rule would also authorize the Board to provide for the settlement of pending transactions of either Division prior to the Transfer Time, so long as the applicable Division's Corporation Default Rule has not been triggered. For example, the Proposed Rule would provide the Board with the ability to, if it deems practicable, based on FICC's resources at that time, allow pending transactions of either Division to complete prior to the transfer of FICC's business to a Transferee. The Board would also have the ability to allow Members to only submit trades to the applicable Division that would effectively offset pending positions or provide that transactions will be processed in accordance with special or exception processing procedures. The Proposed Rule is designed to enable these actions in order to facilitate settlement of pending transactions of the applicable Division and reduce claims against FICC that would have to be satisfied after the transfer has been effected. If none of these actions are deemed practicable (or if the applicable Division's Corporation Default Rule has been triggered with respect to a Division), then the

provisions of the proposed Corporation Default Rule would apply to the treatment of open, pending transactions of such Division.

The Proposed Rule would make clear, however, that neither Division would accept any transactions for processing after the Last Transaction Acceptance Date or which are designated to settle after the Last Settlement Date for such Division. Any transactions to be processed and/or settled after the Transfer Time would be required to be submitted to the Transferee, and would not be FICC's responsibility.

Notice Provisions. The proposed Wind-down Rule would provide that, upon a decision to implement the Winddown Plan, FICC would provide its Members and Limited Members and its regulators with a notice that includes material information relating to the Wind-down Plan and the anticipated transfer of the membership of both Divisions and business, including, for example, (1) a brief statement of the reasons for the decision to implement the Wind-down Plan; (2) identification of the Transferee and information regarding the transaction by which the transfer of FICC's business would be effected; (3) the Transfer Time, Last Transaction Acceptance Date, and Last Settlement Date; and (4) identification of Eligible Members and Eligible Limited Members, and the critical and non-critical services that would be transferred to the Transferee at the Transfer Time, as well as those Non-Eligible Members and Non-Eligible Limited Members (as defined in the Proposed Rule), and any non-critical services that would not be included in the transfer. FICC would also make available the rules and procedures and membership agreements of the Transferee.

Transfer of Membership. The proposed Wind-down Rule would address the expected transfer of both Divisions' membership to the Transferee, which FICC would seek to effectuate by entering into an arrangement with a Failover Transferee, or by using commercially reasonable efforts to enter into such an arrangement with a Third Party Transferee. Therefore, the Wind-down Rule would provide Members, Limited Members and Settling Banks with notice that, in connection with the implementation of the Wind-down Plan and with no further action required by any party, (1) their membership with the applicable Division would transfer to the Transferee, (2) they would become party to a membership agreement with such Transferee, and (3) they would have all of the rights and be subject to all of the

obligations applicable to their membership status under the rules of the Transferee. These provisions would not apply to any Member or Limited Member that is either in default of an obligation to FICC or has provided notice of its election to withdraw its membership from the applicable Division. Further, the proposed Winddown Rule would make clear that it would not prohibit (1) Members and Limited Members that are not transferred by operation of the Winddown Rule from applying for membership with the Transferee, or (2) Members, Limited Members, and Settling Banks that would be transferred to the Transferee from withdrawing from membership with the Transferee.54

Comparability Period. The proposed automatic mechanism for the transfer of both Divisions' memberships is intended to provide the membership with continuous access to critical services in the event of FICC's winddown, and to facilitate the continued prompt and accurate clearance and settlement of securities transactions. Further to this goal, the proposed Winddown Rule would provide that FICC would enter into arrangements with a Failover Transferee, or would use commercially reasonable efforts to enter into arrangements with a Third Party Transferee, providing that, in either case, with respect to the critical services and any non-critical services that are transferred from FICC to the Transferee, for at least a period of time to be agreed upon ("Comparability Period"), the business transferred from FICC to the Transferee would be operated in a manner that is comparable to the manner in which the business was previously operated by FICC. Specifically, the proposed Wind-down Rule would provide that: (1) The rules of the Transferee and terms of membership agreements would be comparable in substance and effect to the analogous Rules and membership agreements of FICC; (2) the rights and obligations of any Members, Limited Members and Settling Banks that are transferred to the Transferee would be comparable in substance and effect to their rights and obligations as to FICC; and (3) the Transferee would operate the transferred business and provide any services that are transferred in a comparable manner to which such services were provided by FICC. The

⁵⁴ The Members and Limited Members whose membership is transferred to the Transferee pursuant to the proposed Wind-down Rule would submit transactions to be processed and settled subject to the rules and procedures of the Transferee, including any applicable margin charges or other financial obligations.

purpose of these provisions and the intended effect of the proposed Winddown Rule is to facilitate a smooth transition of FICC's business to a Transferee and to provide that, for at least the Comparability Period, the Transferee (1) would operate the transferred business in a manner that is comparable in substance and effect to the manner in which the business was operated by FICC, and (2) would not require sudden and disruptive changes in the systems, operations and business practices of the new members of the Transferee.

Subordination of Claims Provisions and Miscellaneous Matters. The proposed Wind-down Rule would also include a provision addressing the subordination of unsecured claims against FICC of its Members and Limited Members who fail to participate in FICC's recovery efforts (i.e., such firms are delinquent in their obligations to FICC or elect to retire from FICC in order to minimize their obligations with respect to the allocation of losses, pursuant to the Rules). This provision is designed to incentivize Members to participate in FICC's recovery efforts. 55

The proposed Wind-down Rule would address other ex-ante matters, including provisions providing that its Members, Limited Members and Settling Banks (1) will assist and cooperate with FICC to effectuate the transfer of FICC's business to a Transferee, (2) consent to the provisions of the rule, and (3) grant FICC power of attorney to execute and deliver on their behalf documents and instruments that may be requested by the Transferee. Finally, the Proposed Rule would include a limitation of liability for any actions taken or omitted to be taken by FICC pursuant to the Proposed Rule. The purpose of the limitation of liability is to facilitate and protect FICC's ability to act expeditiously in response to extraordinary events. As noted, such limitation of liability would be available only following triggering of the Winddown Plan. In addition, and as a separate matter, the limitation of liability provides Members with transparency for the unlikely situation when those extraordinary events could occur, as well supporting the legal framework within which FICC would

take such actions. These provisions, collectively, are designed to enable FICC to take such acts as the Board determines necessary to effectuate an orderly transfer and wind-down of its business should recovery efforts prove unsuccessful.

GSD Rule 50 and MBSD Rule 40 (Market Disruption and Force Majeure)

The proposed GSD Rule 50 and MBSD Rule 40 (Market Disruption and Force Majeure) (collectively, "Force Majeure Rule") would address FICC's authority to take certain actions upon the occurrence, and during the pendency, of a "Market Disruption Event," as defined therein. Because GSD and MBSD are both divisions of FICC, the individual Force Majeure Rules are designed to work together. A decision by the Board or management of FICC that a Market Disruption Event has occurred in accordance with the Force Majeure Rule would trigger the provisions of the Force Majeure Rule of each Division simultaneously. The Proposed Rule is designed to clarify FICC's ability to take actions to address extraordinary events outside of the control of FICC and of the memberships of the Divisions, and to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Force Majeure Rule, FICC would be entitled, during the pendency of a Market Disruption Event, to (1) suspend the provision of any or all services, and (2) take, or refrain from taking, or require its Members and Limited Members to take, or refrain from taking, any actions it considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of FICC's services as may be practicable.

The proposed Force Majeure Rule would identify the events or circumstances that would be considered a "Market Disruption Event," including, for example, events that lead to the suspension or limitation of trading or banking in the markets in which FICC operates, or the unavailability or failure of any material payment, bank transfer, wire or securities settlement systems. The proposed Force Majeure Řule would define the governance procedures for how FICC would determine whether, and how, to implement the provisions of the rule. A determination that a Market Disruption Event has occurred would generally be made by the Board, but the Proposed Rule would provide for limited, interim delegation of authority to a specified officer or management committee if the Board would not be able to take timely

action. In the event such delegated authority is exercised, the proposed Force Majeure Rule would require that the Board be convened as promptly as practicable, no later than five Business Days after such determination has been made, to ratify, modify, or rescind the action. The proposed Force Majeure Rule would also provide for prompt notification to the Commission, and advance consultation with Commission staff, when practicable, including notification when an event is no longer continuing and the relevant actions are terminated. The Proposed Rule would require Members and Limited Members to notify FICC immediately upon becoming aware of a Market Disruption Event, and, likewise, would require FICC to notify Members and Limited Members if it has triggered the Proposed Rule and of actions taken or intended to be taken thereunder.

Finally, the Proposed Rule would address other related matters, including a limitation of liability for any failure or delay in performance, in whole or in part, arising out of the Market Disruption Event. The purpose of the limitation of liability would be similar to the purpose of the analogous provision in the proposed Wind-down Rule, which is to facilitate and protect FICC's ability to act expeditiously in response to extraordinary events.

Proposed Changes to GSD Rules, MBSD Rules, and EPN Rules

In order to incorporate the Proposed Rules into the Rules and the EPN Rules, FICC is also proposing to amend (1) GSD Rule 3A (Sponsoring Members and Sponsored Members), GSD Rule 3B (Centrally Cleared Institutional Triparty Service) and GSD Rule 13 (Funds-Only Settlement); (2) MBSD Rule 3A (Cash Settlement Bank Members); and (3) Rule 1 of the EPN Rules. As shown on Exhibit 5b, these proposed changes would clarify that certain types of Limited Members, as identified in those rules, would be subject to the Proposed Rules.

(a) Statutory Basis

FICC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, FICC believes that the R&W Plan, each of the Proposed Rules and the other proposed changes to the Rules and the EPN Rules are consistent with Section 17A(b)(3)(F) of the Act,⁵⁶ the R&W Plan and each of the Proposed Rules are consistent with

⁵⁵ Nothing in the proposed Wind-down Rule would seek to prevent a Member, Limited Member or Settling Bank that retired its membership at either of the Divisions from applying for membership with the Transferee. Once its FICC membership is terminated, however, such firm would not be able to benefit from the membership assignment that would be effected by this proposed Wind-down Rule, and it would have to apply for membership directly with the Transferee, subject to its membership application and review process.

⁵⁶ 15 U.S.C. 78q-1(b)(3)(F).

Rule 17Ad–22(e)(3)(ii) under the Act,⁵⁷ and the R&W Plan is consistent with Rule 17Ad–22(e)(15)(ii) under the Act,⁵⁸ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of FICC be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible.⁵⁹ The Recovery Plan and the proposed Force Majeure Rule would promote the prompt and accurate clearance and settlement of securities transactions by providing FICC with a roadmap for actions it may employ to mitigate losses, and monitor and, as needed, stabilize, its financial condition, which would allow it to continue its critical clearance and settlement services in stress situations. Further, as described above, the Recovery Plan is designed to identify the actions and tools FICC may use to address and minimize losses to both FICC and Members. The Recovery Plan and the proposed Force Majeure Rule would provide FICC's management and the Board with guidance in this regard by identifying the indicators and governance around the use and application of such tools to enable them to address stress situations in a manner most appropriate for the circumstances. Therefore, the Recovery Plan and the proposed Force Majeure Rule would also contribute to the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible by enabling actions that would address and minimize losses.

The Wind-down Plan and the proposed Wind-down Rule, which would facilitate the implementation of the Wind-down Plan, would also promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible. The Wind-down Plan and the proposed Wind-down Rule would collectively establish a framework for the transfer and orderly wind-down of FICC's business. These proposals would establish clear mechanisms for the transfer of FICC's critical services and membership. By doing so, the Wind-down Plan and this Proposed Rule are designed to facilitate the continuity of FICC's critical services and enable Members and Limited Members to maintain access to FICC's services through the transfer of its

Divisions' memberships in the event the Wind-down Plan is triggered by the Board. Therefore, by facilitating the continuity of FICC's critical clearance and settlement services, FICC believes the proposals would promote the prompt and accurate clearance and settlement of securities transactions. Further, by creating a framework for the transfer and orderly wind-down of FICC's business, FICC believes the proposals would enhance the safeguarding of securities and funds which are in the custody or control of FICC or for which it is responsible.

Finally, the other proposed changes to the Rules and the EPN Rules would clarify the application of the Proposed Rules to certain types of Limited Members and would enable these Limited Members to readily understand their rights and obligations. As such, FICC believes these proposed changes would enable Limited Members that are governed by the applicable rules to have a better understanding of those rules and, thereby, would assist in promoting the prompt and accurate clearance and settlement of securities transactions.

Therefore, FICC believes the R&W Plan, each of the Proposed Rules, and the other proposed changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁶⁰

Rule 17Ad-22(e)(3)(ii) under the Act requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.⁶¹ The R&W Plan and each of the Proposed Rules are designed to meet the requirements of Rule 17Ad-22(e)(3)(ii).62

The R&W Plan would be maintained by FICC in compliance with Rule 17Ad–22(e)(3)(ii) in that it provides plans for the recovery and orderly wind-down of FICC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described above. 63 Specifically, the Recovery Plan would define the risk management activities, stress conditions and indicators, and tools that FICC may

use to address stress scenarios that could eventually prevent it from being able to provide its critical services as a going concern. Through the framework of the Crisis Continuum, the Recovery Plan would address measures that FICC may take to address risks of credit losses and liquidity shortfalls, and other losses that could arise from a Member default. The Recovery Plan would also address the management of general business risks and other non-default risks that could lead to losses.

The Wind-down Plan would be triggered by a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning FICC to viability as a going concern. Once triggered, the Winddown Plan would set forth clear mechanisms for the transfer of the memberships of both Divisions and FICC's business, and would be designed to facilitate continued access to FICC's critical services and to minimize market impact of the transfer. By establishing the framework and strategy for the execution of the transfer and winddown of FICC in order to facilitate continuous access to FICC's critical services, the Wind-down Plan establishes a plan for the orderly winddown of FICC. Therefore, FICC believes the R&W Plan would provide plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, and, as such, meets the requirements of Rule 17Ad-22(e)(3)(ii).64

As described in greater detail above, the Proposed Rules are designed to facilitate the execution of the R&W Plan, provide Members and Limited Members with transparency regarding the material provisions of the Plan, and provide FICC with a legal basis for implementation of those provisions. As such, FICC also believes the Proposed Rules meet the requirements of Rule 17Ad–22(e)(3)(ii).⁶⁵

FICC has evaluated the recovery tools that would be identified in the Recovery Plan and has determined that these tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to Members to manage the risks they present. The recovery tools, as outlined in the Recovery Plan and in the proposed Force Majeure Rule, provide FICC with a comprehensive set of options to address its material risks and support the resiliency of its critical services under a range of stress scenarios. FICC

^{57 17} CFR 240.17Ad-22(e)(3)(ii).

⁵⁸ Id. at 240.17Ad-22(e)(15)(ii).

⁵⁹ 15 U.S.C. 78q-1(b)(3)(F).

⁶⁰ *Id*.

^{61 17} CFR 240.17Ad-22(e)(3)(ii).

⁶² *Id*.

⁶³ *Id*.

⁶⁴ Id.

⁶⁵ Id.

also believes the recovery tools are effective, as FICC has both legal basis and operational capability to execute these tools in a timely and reliable manner. Many of the recovery tools are provided for in the Rules; Members are bound by the Rules through their membership agreements with FICC, and the Rules are adopted pursuant to a framework established by Rule 19b-4 under the Act,66 providing a legal basis for the recovery tools found therein. Other recovery tools have legal basis in contractual arrangements to which FICC is a party, as described above. Further, as many of the tools are embedded in FICC's ongoing risk management practices or are embedded into its predefined default-management procedures, FICC is able to execute these tools, in most cases, when needed and without material operational or organizational delay.

The majority of the recovery tools are also transparent, as they are, or are proposed to be, included in the Rules, which are publicly available. FICC believes the recovery tools also provide appropriate incentives to Members, as they are designed to control the amount of risk they present to FICC's clearance and settlement system. Members' financial obligations to FICC, particularly their required deposits to the applicable Division's Clearing Fund, are measured by the risk posed by the Members' activity in FICC's systems, which incentivizes them to manage that risk which would correspond to lower financial obligations. Finally, FICC's Recovery Plan provides for a continuous evaluation of the systemic consequences of executing its recovery tools, with the goal of minimizing their negative impact. The Recovery Plan would outline various indicators over a timeline of increasing stress, the Crisis Continuum, with escalation triggers to FICC management or the Board, as appropriate. This approach would allow for timely evaluation of the situation and the possible impacts of the use of a recovery tool in order to minimize the negative effects of the stress scenario. Therefore, FICC believes that the recovery tools that would be identified and described in its Recovery Plan, including the authority provided to it in the proposed Force Majeure Rule, would meet the criteria identified within guidance published by the Commission in connection with the adoption of Rule 17Ad-22(e)(3)(ii).67

Therefore, FICC believes the R&W Plan and each of the Proposed Rules are consistent with Rule 17Ad–22(e)(3)(ii).⁶⁸

Rule 17Ad-22(e)(15)(ii) under the Act requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage its general business risk and hold sufficient LNA to cover potential general business losses so that FICC can continue operations and services as a going concern if those losses materialize, including by holding LNA equal to the greater of either (x) six months of the covered clearing agency's current operating expenses, or (y) the amount determined by the board of directors to be sufficient to ensure a recovery or orderly wind-down of critical operations and services of the covered clearing agency. 69 While the Capital Policy addresses how FICC holds LNA in compliance with these requirements, the Wind-down Plan would include an analysis that would estimate the amount of time and the costs to achieve a recovery or orderly wind-down of FICC's critical operations and services, and would provide that the Board review and approve this analysis and estimation annually. The Wind-down Plan would also provide that the estimate would be the "Recovery/Winddown Capital Requirement" under the Capital Policy. Under that policy, the General Business Risk Capital Requirement, which is the sufficient amount of LNA that FICC should hold to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize, is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement. Therefore, FICC believes the R&W Plan, as it interrelates with the Capital Policy, is consistent with Rule 17Ad-22(e)(15)(ii).70

(B) Clearing Agency's Statement on Burden on Competition

FICC does not believe the proposal would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act.⁷¹ The proposal would apply uniformly to all Members and Limited Members. FICC does not anticipate that the proposal would affect its day-to-day operations under normal circumstances, or in the management of a typical Member default scenario or non-default event. FICC is not proposing to alter the standards or requirements

for becoming or remaining a Member, or otherwise using its services. FICC also does not propose to change either Division's methodology for calculation of margin or their respective Clearing Fund contributions. The proposal is intended to (1) address the risk of loss events and identify the tools and resources available to it to withstand and recover from such events, so that it can restore normal operations, and (2) provide a framework for its orderly wind-down and the transfer of its business in the event those recovery tools do not restore FICC to financial viability, as described herein.

The Ř&W Plan and each of the Proposed Rules have been developed and documented in order to satisfy applicable regulatory requirements, as discussed above.

With respect to the Recovery Plan, the proposal generally reflects FICC's existing tools and existing internal procedures. Existing tools that would have a direct impact on the rights, responsibilities or obligations of Members are reflected in the existing Rules or are proposed to be included in the Rules. Accordingly, the Recovery Plan and the proposed Force Majeure Rule are intended to provide a roadmap, define the strategy and identify the tools available to FICC in connection with its recovery efforts. By proposing to enhance FICC's existing internal management and its regulatory compliance related to its recovery efforts, FICC does not believe the Recovery Plan or the proposed Force Majeure Rule would have any impact, or impose any burden, on competition.

With respect to the Wind-down Plan and the proposed Wind-down Rule, which facilitate the execution of the Wind-down Plan, the proposal would operate to effect the transfer of all eligible Members and Limited Members of both Divisions to the Transferee, and would not prohibit any market participant from either bidding to become the Transferee or from applying for membership with the Transferee. The proposal also would not prohibit any Member or Limited Member from withdrawing from FICC prior to the Transfer Time, as is permitted under the Rules today, or from applying for membership with the Transferee. Therefore, as the proposal would treat each similarly situated Member identically under the Wind-down Plan and this Proposed Rule, FICC does not believe the Wind-down Plan or the proposed Wind-down Rule would have any impact, or impose any burden, on competition.

FICC does not believe that the other proposed changes to the Rules and the

⁶⁶ Id. at 240.19b-4.

⁶⁷ Supra note 45.

⁶⁸ 17 CFR 240.17Ad–22(e)(3)(ii).

⁶⁹ Id. at 240.17Ad-22(e)(15)(ii).

⁷⁰ Id.

^{71 15} U.S.C. 78q-1(b)(3)(I).

EPN Rules would have any impact on competition because these proposed changes to incorporate the Proposed Rules into the Rules and the EPN Rules are technical clarifications, which would not, on their own, change FICC's current practices or the rights or obligations of the Members or EPN Users.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

While FICC has not solicited or received any written comments relating to this proposal, FICC has conducted outreach to its Members in order to provide them with notice of the proposal. FICC will notify the Commission of any written comments received by FICC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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–FICC-2017-021 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-FICC-2017-021. 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 website (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 website 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 FICC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-FICC-2017-021 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 72

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15365 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83633; File No. SR-NSCC-2017-018]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Amend the Loss Allocation Rules and Make Other Changes

July 13, 2018.

On December 18, 2017, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–NSCC–2017–018 ("Proposed Rule Change") to amend the loss allocation rules and make other changes; the Proposed Rule Change was published for comment in the **Federal Register** on January 8, 2018.¹ On

February 8, 2018, the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.² On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change; on June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the Proposed Rule Change.³ On June 28, 2018, NSCC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.4 As of the date of this release, the Commission has not received any

No. 82584 (January 24, 2018), 83 FR 4377 (January 30, 2018) (SR-NSCC-2017-806). On April 10, 2018, the Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled ''Commission's Request for Additional Information," available at https:// www.sec.gov/rules/sro/nscc-an.htm. On June 28, 2018, NSCC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, NSCC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/nscc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(E) and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at https://www.sec.gov/ rules/sro/nscc-an.htm. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

Securities Exchange Act Release No. 82670
 (February 8, 2018), 83 FR 6626 (February 14, 2018)
 (SR-DTC-2017-022; SR-FICC-2017-022; SR-NSCC-2017-018).

³ Securities Exchange Act Release No. 82910 (March 20, 2018), 83 FR 12968 (March 26, 2018) (SR–NSCC–2017–018); Securities Exchange Act Release No. 83510 (June 25, 2018), 83 FR 30791 (June 29, 2018) (SR–DTC–2017–022; SR–FICC–2017–022; SR–NSCC–2017–018).

⁴To promote the public availability and transparency of its post-notice amendment, NSCC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the Commission's website at https://www.sec.gov/rules/sro/nscc.htm and thus been publicly available since June 29, 2018.

^{72 17} CFR 200.30–3(a)(12).

¹¹⁵ U.S.C. 78s(b)(1) and 17 CFR 240.19b-4. respectively. Securities Exchange Act Release No. 82428 (January 2, 2018), 83 FR 897 (January 8, 2018) (SR-NSCC-2017-018). On December 18, 2017, NSCC filed the Proposed Rule Change as advance notice SR-NSCC-2017-806 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release

comments on the Proposed Rule Change.

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by NSCC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of modifications to NSCC's Rules and Procedures ("Rules") in order to amend provisions in the Rules regarding loss allocation as well as make other changes, as described in greater detail below.⁵

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of Amendment No. 1

This filing constitutes Amendment No. 1 ("Amendment") to rule filing SR–NSCC–2017–018 ("Rule Filing") previously filed by NSCC on December 18, 2017.6 This Amendment amends and replaces the Rule Filing in its entirety. NSCC submits this Amendment in order to further clarify the operation of the proposed rule changes on loss allocation by providing additional information and examples. In particular, this Amendment would:

(i) Clarify which Members would be subject to loss allocation with respect to Defaulting Member Events (as defined below and in the proposed rule change) and Declared Non-Default Loss Events (as defined below and in the proposed rule change) occurring during an Event

Period (as defined below and in the proposed rule change). Specifically, pursuant to the Amendment, proposed Section 4 of Rule 4 would provide that each Member that is a Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member (as defined below and in the proposed rule change)) and each Declared Non-Default Loss Event occurring during the Event Period. Proposed Section 4 of Rule 4 would also make it clear that any Member for which NSCC ceases to act on a non-business day, triggering an Event Period that commences on the next business day, would be deemed to be a Member on the first day of that Event Period.

(ii) Clarify the obligations and Loss Allocation Cap (as defined below and in the proposed rule change) of a Member that withdraws from membership in respect of a loss allocation round. Specifically, pursuant to the Amendment, proposed Section 6 of Rule 4 would provide that the Member would nevertheless remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under Rule 4; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap as fixed in the round for which it withdrew.

(iii) Clarify that a Member would be obligated to NSCC for all losses and liabilities incurred by NSCC arising out of or relating to any Defaulting Member Event with respect to the Member. Specifically, pursuant to the Amendment, proposed Section 4 of Rule 4 would provide that each Member would be obligated to NSCC for the entire amount of any loss or liability incurred by NSCC arising out of or relating to any Defaulting Member Event with respect to such Member.

(iv) Clarify that, although a Defaulting Member would not be allocated a ratable share of losses and liabilities arising out of or relating to its own Defaulting Member Event, it would remain obligated to NSCC for all such losses and liabilities. Specifically, pursuant to the Amendment, proposed Section 10 of Rule 4 would provide that no loss allocation under Rule 4 would constitute a waiver of any claim NSCC may have against a Member for any loss or liability to which the Member is subject under the Rules, including, without limitation, any loss or liability to which it may be subject under Rule

In addition, pursuant to the Amendment, NSCC is making other clarifying and technical changes to the proposed rule change, as proposed herein.

Nature of the Proposed Change

The primary purpose of this proposed rule change is to amend NSCC's loss allocation rules in order to enhance the resiliency of NSCC's loss allocation process so that NSCC can take timely action to address multiple loss events that occur in succession during a short period of time (defined and explained in detail below). In connection therewith, the proposed rule change would (i) align the loss allocation rules of the three clearing agencies of The Depository Trust & Clearing Corporation ("DTCC"), namely The Depository Trust Company ("DTC"), Fixed Income Clearing Corporation ("FICC") (including the Government Securities Division ("FICC/ GSD") and the Mortgage-Backed Securities Division ("FICC/MBSD")), and NSCC (collectively, the "DTCC Clearing Agencies"), so as to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies, (ii) increase transparency and accessibility of the loss allocation rules by enhancing their readability and clarity, (iii) reduce the time within which NSCC is required to return a former Member's Clearing Fund deposit, (iv) increase clarity of the voluntary termination provisions, and (v) make conforming and technical changes.

(i) Background

Central counterparties ("CCPs") play a key role in financial markets by mitigating counterparty credit risk on transactions between market participants. CCPs achieve this by providing guaranties to participants and, as a consequence, are typically exposed to credit risks that could lead to default losses. In addition, in performing its critical functions, a CCP could be exposed to non-default losses that are otherwise incident to the CCP's clearance and settlement business.

A CCP's rulebook should provide a complete description of how losses would be allocated to participants if the size of the losses exceeded the CCP's pre-funded resources. Doing so provides for an orderly allocation of losses, and potentially allows the CCP to continue providing critical services to the market and thereby results in significant financial stability benefits. In addition, a clear description of the loss allocation process offers transparency and accessibility to the CCP's participants.

⁵Capitalized terms not defined herein are defined in the Rules, available at http://www.dtcc.com/~/ media/Files/Downloads/legal/rules/nscc_rules.pdf.

⁶ See Securities Exchange Act Release No. 82428 (January 2, 2018), 83 FR 897 (January 8, 2018) (SR-NSCC-2017-018).

Current NSCC Loss Allocation Process

As a CCP, NSCC's loss allocation process is a key component of its risk management process. Risk management is the foundation of NSCC's ability to guarantee settlement, as well as the means by which NSCC protects itself and its Members from the risks inherent in the clearance and settlement process. NSCC's risk management process must account for the fact that, in certain extreme circumstances, the collateral and other financial resources that secure NSCC's risk exposures may not be sufficient to fully cover losses resulting from the liquidation of the portfolio of a Member for whom NSCC has ceased to act.7

The Rules currently provide for a loss allocation process through which both NSCC (by applying no less than 25% of its retained earnings in accordance with Addendum E) and its Members would share in the allocation of a loss resulting from the default of a Member for whom NSCC has ceased to act pursuant to the Rules. The Rules also recognize that NSCC may incur losses outside the context of a defaulting Member that are otherwise incident to NSCC's clearance and settlement business.

NSCC's loss allocation rules currently provide that in the event NSCC ceases to act for a Member, the amounts on deposit to the Clearing Fund from the defaulting Member, along with any other resources of, or attributable to, the defaulting Member that NSCC may access under the Rules (e.g., payments from Clearing Agency Cross-Guaranty Agreements), are the first source of funds NSCC would use to cover any losses that may result from the closeout of the defaulting Member's guaranteed positions. If these amounts are not sufficient to cover all losses incurred, then NSCC will apply the following available resources, in the following loss allocation waterfall order:

First, as provided in Addendum E, NSCC's corporate contribution of at least 25 percent of NSCC's retained earnings existing at the time of a Member impairment, or such greater amount as the Board of Directors may determine; and

Second, if a loss still remains, as and in the manner provided in Rule 4, the required Clearing Fund deposits of Members who are non-defaulting Members on the date of default.

Pursuant to current Section 5 of Rule 4, if, as a result of applying the Clearing Fund deposit of a Member, the Member's actual Clearing Fund deposit is less than its Required Deposit, it will be required to eliminate such deficiency in order to satisfy its Required Deposit amount. Pursuant to current Section 4 of Rule 4, Members can also be assessed for non-default losses incident to the operation of the clearance and settlement business of NSCC. Pursuant to current Section 8 of Rule 4, Members may withdraw from membership within specified timeframes after a loss allocation charge to limit their obligation for future assessments.

Overview of the Proposed Rule Changes

A. Changes To Enhance Resiliency of NSCC's Loss Allocation Process

In order to enhance the resiliency of NSCC's loss allocation process, NSCC proposes to change the manner in which each of the aspects of the loss allocation waterfall described above would be employed. NSCC would retain the current core loss allocation process following the application of the defaulting Member's resources, i.e., first, by applying NSCC's corporate contribution, and second, by pro rata allocations to Members. However, NSCC would clarify or adjust certain elements and introduce certain new loss allocation concepts, as further discussed below. In addition, the proposed rule change would address the loss allocation process as it relates to losses arising from or relating to multiple default or non-default events in a short period of time, also as described below.

Accordingly, NSCC is proposing five (5) key changes to enhance NSCC's loss allocation process:

(1) Changing the calculation and application of NSCC's corporate contribution.

As stated above, Addendum E currently provides that NSCC will contribute no less than 25% of its retained earnings (or such higher amount as the Board of Directors shall determine) to a loss or liability that is not satisfied by the impaired Member's Clearing Fund deposit. Under the proposal, NSCC would amend the calculation of its corporate contribution from a percentage of its retained earnings to a mandatory amount equal to 50% of the NSCC General Business Risk Capital Requirement.⁸ NSCC's

General Business Risk Capital Requirement, as defined in NSCC's Clearing Agency Policy on Capital Requirements,⁹ is, at a minimum, equal to the regulatory capital that NSCC is required to maintain in compliance with Rule 17Ad–22(e)(15) under the Act.¹⁰ The proposed Corporate Contribution (as defined in the proposed rule change) would be held in addition to NSCC's General Business Risk Capital Requirement.

Currently, the Rules do not require NSCC to contribute its retained earnings to losses and liabilities other than those from Member impairments. Under the proposal, NSCC would apply its corporate contribution to non-default losses as well. The proposed Corporate Contribution would apply to losses arising from Defaulting Member Events and Declared Non-Default Loss Events (as such terms are defined below and in the proposed rule change), and would be a mandatory contribution by NSCC prior to any allocation of the loss among NSCC's Members.¹¹ As proposed, if the Corporate Contribution is fully or partially used against a loss or liability relating to an Event Period, the Corporate Contribution would be reduced to the remaining unused amount, if any, during the following two hundred fifty (250) business days¹² in order to permit NSCC to replenish the Corporate Contribution. ¹³ To ensure transparency, Members would receive

⁷ When NSCC restricts a Member's access to services generally, NSCC is said to have "ceased to act" for the Member. Rule 46 (Restrictions on Access to Services) sets out the circumstances under which NSCC may cease to act for a Member, and Rule 18 (Procedures for When the Corporation Declines or Ceases to Act) sets out the types of actions NSCC may take when it ceases to act for a Member. Supra note 5.

⁸ NSCC calculates its General Business Risk Capital Requirement as the amount equal to the greatest of (i) an amount determined based on its general business profile, (ii) an amount determined

based on the time estimated to execute a recovery or orderly wind-down of NSCC's critical operations, and (iii) an amount determined based on an analysis of NSCC's estimated operating expenses for a six (6) month period.

⁹ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR– NSCC–2017–004).

^{10 17} CFR 240.17Ad-22(e)(15).

¹¹ The proposed rule change would not require a Corporate Contribution with respect to the use of the Clearing Fund as a liquidity resource; however, if NSCC uses the Clearing Fund as a liquidity resource for more than 30 calendar days, as set forth in proposed Section 2 of Rule 4, then NSCC would have to consider the amount used as a loss to the Clearing Fund incurred as a result of a Defaulting Member Event and allocate the loss pursuant to proposed Section 4 of Rule 4, which would then require the application of a Corporate Contribution.

¹² Rule 1 defines "business day" as "any day on which the Corporation is open for business. However, on any business day that banks or transfer agencies in New York State are closed or a Qualified Securities Depository is closed, no deliveries of securities and no payments of money shall be made through the facilities of the Corporation." Supra note 5.

¹³ NSCC believes that two hundred and fifty (250) business days would be a reasonable estimate of the time frame that NSCC would require to replenish the Corporate Contribution by equity in accordance with NSCC's Clearing Agency Policy on Capital Requirements, including a conservative additional period to account for any potential delays and/or unknown exigencies in times of distress.

notice of any such reduction to the Corporate Contribution.

As compared to the current approach of applying "no less than" a percentage of retained earnings to defaulting Member losses, the proposed Corporate Contribution would be a fixed percentage of NSCC's General Business Risk Capital Requirement, which would provide greater transparency and accessibility to Members. The proposed Corporate Contribution would apply not only towards losses and liabilities arising out of or relating to Defaulting Member Events but also those arising out of or relating to Declared Non-Default Loss Events, which is consistent with the current industry guidance that "a CCP should identify the amount of its own resources to be applied towards losses arising from custody and investment risk, to bolster confidence that participants' assets are prudently safeguarded."14

Under the current Addendum E, NSCC has the discretion to contribute amounts higher than the specified percentage of retained earnings, as determined by the Board of Directors, to any loss or liability incurred by NSCC as result of a Member's impairment. This option would be retained and expanded under the proposal so that it would be clear that NSCC can voluntarily apply amounts greater than the Corporate Contribution against any loss or liability (including non-default losses) of NSCC, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation existing at the time.

The proposed rule changes relating to the calculation and application of the Corporate Contribution are set forth in proposed Sections 4 and 5 of Rule 4, as further described below.

(2) Introducing an Event Period. In order to clearly define the obligations of NSCC and its Members regarding loss allocation and to balance the need to manage the risk of sequential loss events against Members' need for certainty concerning their maximum loss allocation exposures, NSCC is proposing to introduce the concept of an "Event Period" to the Rules to address the losses and liabilities that may arise from or relate to multiple Defaulting Member Events and/or Declared Non-Default Loss Events that arise in quick succession. Specifically, the proposal would group Defaulting Member Events and Declared

Non-Default Loss Events occurring in a period of ten (10) business days ("Event Period") for purposes of allocating losses to Members in one or more rounds (as described below), subject to the limitations of loss allocation set forth in the proposed rule change and as explained below.¹⁵ In the case of a loss or liability arising from or relating to a Defaulting Member Event, an Event Period would begin on the day NSCC notifies Members that it has ceased to act ¹⁶ for the Defaulting Member (or the next business day, if such day is not a business day). In the case of a loss or liability arising from or relating to a Declared Non-Default Loss Event, an Event Period would begin on the day that NSCC notifies Members of the Declared Non-Default Loss Event (or the next business day, if such day is not a business day). If a subsequent Defaulting Member Event or Declared Non-Default Loss Event occurs during an Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period. An Event Period may include both Defaulting Member Events and Declared Non-Default Loss Events, and there would not be separate Event Periods for Defaulting Member Events or Declared Non-Default Loss Events occurring during overlapping ten (10) business day periods.

The amount of losses that may be allocated by NSCC, subject to the required Corporate Contribution, and to which a Loss Allocation Cap would apply for any Member that elects to withdraw from membership in respect of a loss allocation round, would include any and all losses from any Defaulting Member Events and any Declared Non-Default Loss Events during the Event Period, regardless of the amount of time, during or after the Event Period, required for such losses to be crystallized and allocated. 17

The proposed rule changes relating to the implementation of an Event Period are set forth in proposed Section 4 of Rule 4, as further described below. (3) Introducing the concept of

"rounds" and Loss Allocation Notice. Pursuant to the proposed rule change, a loss allocation "round" would mean a series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the sum of the Loss Allocation Caps of affected Members (a "round cap"). When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. NSCC may continue the loss allocation process in successive rounds until all losses from the Event Period are

allocated among Members that have not

submitted a Loss Allocation Withdrawal

Notice in accordance with proposed

Section 6 of Rule 4.

Each loss allocation would be communicated to Members by the issuance of a notice that advises the Members of the amount being allocated to them ("Loss Allocation Notice"). Each Member's pro rata share of losses and liabilities to be allocated in any round would be equal to (i) the average of its Required Fund Deposit for the seventy (70) business days preceding the first day of the applicable Event Period or such shorter period of time that the Member has been a Member (each Member's "Average RFD"), divided by (ii) the sum of Average RFD amounts of all Members subject to loss allocation in such round.

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Member in that round has five (5) business days from the issuance of such first Loss Allocation Notice for the round to notify NSCC of its election to withdraw from membership with NSCC pursuant to proposed Section 6 of Rule 4, and thereby benefit from its Loss Allocation Cap. 18 The "Loss Allocation Cap" of a

¹⁴ See Resilience of central counterparties (CCPs): Further guidance on the PFMI, issued by the Committee on Payments and Market Infrastructures and the International Organization of Securities Commissions, at 42 (July 2017), available at www.bis.org/cpmi/publ/d163.pdf.

¹⁵ NSCC believes that having a ten (10) business day Event Period would provide a reasonable period of time to encompass potential sequential Defaulting Member Events or Declared Non-Default Loss Events that are likely to be closely linked to an initial event and/or a severe market dislocation episode, while still providing appropriate certainty for Members concerning their maximum exposure to mutualized losses with respect to such events.

¹⁶ Supra note 7.

¹⁷ As discussed below, each Member that is a Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member) and each Declared Non-Default Loss Event occurring during the Event Period.

¹⁸ Pursuant to the current Section 8 of Rule 4, the time period for a participant to give notice of its election to terminate its business with NSCC in respect of a pro rata charge is ten (10) business days after receiving notice of a pro rata charge. *Supra*

NSCC believes that it is appropriate to shorten such time period from ten (10) business days to five (5) business days because NSCC needs timely notice

Member would be equal to the greater of (x) its Required Fund Deposit on the first day of the applicable Event Period and (y) its Average RFD.

After a first round of loss allocations with respect to an Event Period, only Members that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 6 of Rule 4 would be subject to further loss allocation with respect to that Event Period.

The amount of any second or subsequent round cap may differ from the first or preceding round cap because there may be fewer Members in a second or subsequent round if Members elect to withdraw from membership with NSCC as provided in proposed Section 6 of Rule 4 following the first Loss Allocation Notice in any round.

For example, for illustrative purposes only, after the required Corporate Contribution, if NSCC has a \$5 billion loss determined with respect to an Event Period and the sum of Loss Allocation Caps for all Members subject to the loss allocation is \$4 billion, the first round would begin when NSCC issues the first Loss Allocation Notice for that Event Period. NSCC could issue one or more Loss Allocation Notices for the first round until the sum of losses allocated equals \$4 billion. Once the \$4 billion is allocated, the first round would end and NSCC would need a second round in order to allocate the remaining \$1 billion of loss. NSCC would then issue a Loss Allocation Notice for the \$1 billion and this notice would be the first Loss Allocation Notice for the second round. The issuance of the Loss Allocation Notice for the \$1 billion would begin the second round.

The proposed rule change would link the Loss Allocation Cap to a round in order to provide Members the option to limit their loss allocation exposure at the beginning of each round. As proposed and as described further below, a Member could limit its loss allocation exposure to its Loss Allocation Cap by providing notice of its election to withdraw from membership within five (5) business days after the issuance of the first Loss Allocation Notice in any round.

The proposed rule changes relating to the implementation of "rounds" and Loss Allocation Notices are set forth in

of which Members would remain in its membership for purposes of calculating the loss allocation for any subsequent round. NSCC believes that five (5) business days would provide Members with sufficient time to decide whether to cap their loss allocation obligations by withdrawing from their membership in NSCC.

proposed Section 4 of Rule 4, as further described below.

(4) Implementing a "look-back" period to calculate a Member's loss allocation pro rata share and its Loss Allocation Cap.

Currently, the Rules calculate a Member's pro rata share for purposes of loss allocation based on the Member's "allocation for a System," which in turn is based on settlement dollar amounts. Therefore, a Member's loss allocation obligations are currently based on the Member's activity in each of the various services or "Systems" offered by NSCC.¹⁹ The Rules do not anticipate the possibility of more than one Defaulting Member Ěvent or Declared Non-Default Loss Event in quick succession.

Given NSCC's risk-based margining methodology, NSCC believes that it would be more appropriate to determine a Member's pro rata share of losses and liabilities based on the amount of risk that the Member brings to NSCC, which is represented by the Member's Required Deposit (NSCC is proposing that "Required Deposits" be renamed "Required Fund Deposits," as described below). Accordingly, NSCC is proposing to calculate each Member's pro rata share of losses and liabilities to be allocated in any round (as described above and in the proposed rule change) to be equal to (i) the Member's Average RFD divided by (ii) the sum of Average RFD amounts for all Members that are subject to loss allocation in such round.

Additionally, as described above and in the proposed rule change, if a Member withdraws from membership pursuant to proposed Section 6 of Rule 4, NSCC is proposing that the Member's Loss Allocation Cap be equal to the greater of (i) its Required Fund Deposit on the first day of the applicable Event Period or (ii) its Average RFD.

NSCC believes that employing a backward-looking average to calculate a Member's loss allocation pro rata share and Loss Allocation Cap would disincentivize Member behavior that could heighten volatility or reduce liquidity in markets in the midst of a financial crisis. Specifically, the proposed look-back period would discourage a Member from reducing its settlement activity during a time of stress primarily to limit its loss allocation pro rata share, which, as proposed, would now be based on the Member's average settlement activity over the look-back period rather than its settlement activity at a point in time that the Member may not be able to

estimate. Similarly, NSCC believes that taking a backward-looking average into consideration when determining a Member's Loss Allocation Cap would also deter a Member from reducing its settlement activity during a time of stress primarily to limit its Loss Allocation Cap.

NSCC believes that having a look-back period of seventy (70) business days is appropriate, because it would be long enough to enable NSCC to capture a full calendar quarter of a Member's activities, including quarterly option expirations, and smooth out the impact from any abnormalities and/or arbitrariness that may have occurred, but not too long that the Member's business strategy and outlook could have shifted significantly, resulting in material changes to the size of its portfolios.

The proposed rule changes relating to the implementation of a look-back period are set forth in proposed Section 4 of Rule 4, as further described below.

(5) Capping withdrawing Members' loss allocation exposure and related

changes.

NSCC's current loss allocation rules allow a Member to withdraw if the Member notifies NSCC, within ten (10) business days after receipt of notice of a pro rata charge, of its election to terminate its membership and thereby avail itself of a cap on loss allocation, which is its Required Deposit as fixed immediately prior to the time of the pro rata charge. As discussed above, the proposed rule change would continue providing Members the opportunity to limit their loss allocation exposure by offering withdrawal options; however, the cap on loss allocation would be calculated differently and the associated withdrawal process would also be modified as it relates to withdrawals associated with the loss allocation process. In particular, the proposed rule change would shorten the withdrawal notification period from ten (10) business days to five (5) business days, and would also change the beginning of such notification period from the receipt of the notice of a pro rata charge to the issuance of the notice, as further described below.

As proposed, if a Member timely provides notice of its withdrawal from membership in respect of a loss allocation round, the maximum amount of losses it would be responsible for would be its Loss Allocation Cap,²⁰ provided that the Member complies with the requirements of the withdrawal

 $^{^{19}}$ NSCC's current loss allocation rules pre-date NSCC's move to a risk-based margining methodology.

 $^{^{\}rm 20}\,{\rm If}$ a Member's Loss Allocation Cap exceeds the Member's then-current Required Fund Deposit, it must still cover the excess amount.

process in proposed Section 6 of Rule 4.21

Currently, NSCC's loss allocation provisions provide that if a pro rata charge is made against a Member's actual Clearing Fund deposit, and as result thereof the Member's deposit is less than its Required Deposit, the Member will, upon demand by NSCC, be required to replenish its deposit to eliminate the deficiency within such time as NSCC shall require. To increase transparency of the timeframe under which NSCC would require funds from Members to satisfy their loss allocation obligations, NSCC is proposing that Members would receive two (2) business days' notice of a loss allocation, and Members would be required to pay the requisite amount no later than the second business day following issuance of such notice.22 Members would have five (5) business days 23 from the issuance of the first Loss Allocation Notice in any round of an Event Period to decide whether to withdraw from membership.24

Each round would allow a Member the opportunity to notify NSCC of its election to withdraw from membership after satisfaction of the losses allocated in such round. Multiple Loss Allocation Notices may be issued with respect to each round to allocate losses up to the round cap.

Specifically, the first round and each subsequent round of loss allocation would allocate losses up to a round cap of the aggregate of all Loss Allocation Caps of those Members included in the round. If a Member provides notice of its election to withdraw from membership, it would be subject to loss allocation in that round, up to its Loss Allocation Cap. If the first round of loss allocation does not fully cover NSCC's losses, a second round will be noticed to those Members that did not elect to withdraw from membership in the previous round; however, as noted above, the amount of any second or subsequent round cap may differ from the first or preceding round cap because there may be fewer Members in a second or subsequent round if Members elect to withdraw from membership with NSCC as provided in proposed Section 6 of Rule 4 following the first Loss Allocation Notice in any round.

Pursuant to the proposed rule change, in order to avail itself of its Loss Allocation Cap, a Member would need to follow the requirements in proposed Section 6 of Rule 4, which would provide that the Member must: (i) Specify in its Loss Allocation Withdrawal Notice (as defined below and in the proposed rule change) an effective date of withdrawal, which date shall be no later than ten (10) business days following the last day of the applicable Loss Allocation Withdrawal Notification Period (as defined below and in the proposed rule change) (i.e., no later than ten (10) business days after the 5th business day following the first Loss Allocation Notice in that round of loss allocation),25 (ii) cease all activity that would result in transactions being submitted to NSCC for clearance and settlement for which such Member would be obligated to perform, where the scheduled final settlement date would be later than the effective date of the Member's withdrawal, and (iii) ensure that all clearance and settlement activity for which such Member is obligated to NSCC is fully and finally settled by the effective date of the Member's withdrawal, including, without limitation, by resolving by such date all fails and buy-in obligations.

As proposed, a Member that withdraws in compliance with proposed Section 6 of Rule 4 would remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under Rule 4; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap (as fixed in the round for which it withdrew).

The proposed rule changes are designed to enable NSCC to continue the loss allocation process in successive rounds until all of NSCC's losses are allocated. To the extent that a Member's Loss Allocation Cap exceeds the Member's Required Fund Deposit on the first day of the applicable Event Period, NSCC may in its discretion retain any excess amounts on deposit from the

Member, up to the Member's Loss Allocation Cap.

The proposed rule changes relating to capping withdrawing Members' loss allocation exposure and related changes to the withdrawal process are set forth in proposed Sections 4 and 6 of Rule 4, as further described below.

B. Changes To Align Loss Allocation Rules

The proposed rule changes would align the loss allocation rules, to the extent practicable and appropriate, of the three DTCC Clearing Agencies so as to provide consistent treatment, especially for firms that are participants of two or more DTCC Clearing Agencies. As proposed, the loss allocation waterfall and certain related provisions, e.g., returning a former Member's Clearing Fund, would be consistent across the DTCC Clearing Agencies to the extent practicable and appropriate. The proposed rule changes of NSCC that would align loss allocation rules of the DTCC Clearing Agencies are set forth in proposed Sections 1, 2, 7, and 12 of Rule 4, as further described below.

C. Clarifying Changes Relating to Loss Allocation

The proposed rule changes are intended to make the provisions in the Rules governing loss allocation more transparent and accessible to Members. In particular, NSCC is proposing the following changes relating to loss allocation to clarify Members' obligations for Declared Non-Default Loss Events.

Aside from losses that NSCC might face as a result of a Defaulting Member Event, NSCC could incur non-default losses incident to its clearance and settlement business.²⁶ The Rules currently permit NSCC to apply Clearing Fund to non-default losses. Specifically, pursuant to Section 2(b) of Rule 4.27 NSCC can use the Clearing Fund to satisfy losses or liabilities of NSCC incident to the operation of the clearance and settlement business of NSCC. Section II of Addendum K provides additional details regarding the application of the Clearing Fund to losses outside of a System.

If there is a failure of NSCC following a non-default loss, such occurrence would affect Members in much the same

²¹For the avoidance of doubt, pursuant to Section 13(d) of Rule 4(A) (Supplemental Liquidity Deposits), a Special Activity Supplemental Deposit of a Member may not be used to calculate or be applied to satisfy any pro rata charge pursuant to Section 4 of Rule 4. Supra note 5.

²² NSCC believes that allowing Members two (2) business days to satisfy their loss allocation obligations would provide Members sufficient notice to arrange funding, if necessary, while allowing NSCC to address losses in a timely manner.

 $^{^{23}}$ Supra note 18.

²⁴ NSCC believes that setting the start date of the withdrawal notification period to the date of issuance of a notice would provide a single withdrawal timeframe that would be consistent across the Members.

²⁵ NSCC believes that having an effective date of withdrawal that is not later than ten (10) business days following the last day of the Loss Allocation Withdrawal Notification Period would provide Members with a reasonable period of time to wind down their activities at NSCC while minimizing any uncertainty typically associated with a longer withdrawal period.

²⁶ Non-default losses may arise from events such as damage to physical assets, a cyber-attack, or custody and investment losses.

²⁷ Section 2(b) of Rule 4 provides that "the use of the Clearing Fund . . . shall be limited to satisfaction of losses or liabilities of the Corporation incident to the operation of the clearance and settlement business of the Corporation other than losses and liabilities of a System." *Supra* note 5.

way as a failure of NSCC following a Defaulting Member Event. Accordingly, NSCC is proposing rule changes to enhance the provisions relating to non-default losses by clarifying Members' obligations for such losses.

Specifically, NSCC is proposing enhancement of the governance around non-default losses that would trigger loss allocation to Members by specifying that the Board of Directors would have to determine that there is a non-default loss that may be a significant and substantial loss or liability that may materially impair the ability of NSCC to provide clearance and settlement services in an orderly manner and will potentially generate losses to be mutualized among the Members in order to ensure that NSCC may continue to offer clearance and settlement services in an orderly manner. The proposed rule change would provide that NSCC would then be required to promptly notify Members of this determination, which is referred to in the proposed rule as a Declared Non-Default Loss Event. In addition, NSCC is proposing to better align the interests of NSCC with those of its Members by stipulating a mandatory Corporate Contribution apply to a Declared Non-Default Loss Event prior to any allocation of the loss among Members, as described above. Additionally, NSCC is proposing language to clarify Members' obligations for Declared Non-Default Loss Events.

The proposed rule changes relating to Declared Non-Default Loss Events and Members' obligations for such events are set forth in proposed Section 4 of Rule 4, as further described below.

D. Reduce the Time Within Which NSCC Is Required To Return a Former Member's Clearing Fund Deposit

The proposed rule change would reduce the time period in which NSCC may retain a Member's Clearing Fund deposit. Specifically, NSCC proposes that if a Member gives notice to NSCC of its election to withdraw from membership, NSCC will return the Member's Actual Deposit in the form of (i) cash or securities within thirty (30) calendar days and (ii) Eligible Letters of Credit within ninety (90) calendar days, after all of the Member's transactions have settled and all matured and contingent obligations to NSCC for which the Member was responsible while a Member have been satisfied, except NSCC may retain for up to two (2) years the Actual Deposits from Members who have Sponsored Accounts at DTC.

NSCC believes that shortening the time period for the return of a Member's

Clearing Fund deposit would be helpful to firms who have exited NSCC so that they could have use of the deposits sooner than under the current Rules while at the same time protecting NSCC because such return would only occur if all obligations of the terminating Member to NSCC have been satisfied, which would include both matured as well as contingent obligations.

The proposed rule changes relating to the reduced time period in which NSCC is required to return the Clearing Fund deposit of a former Member are set forth in proposed Section 7 of Rule 4, as further described below.

The foregoing changes as well as other changes (including a number of conforming and technical changes) that NSCC is proposing in order to improve the transparency and accessibility of the Rules are described in detail below.

E. Loss Allocation Waterfall Comparison

The following example ²⁸ illustrates the differences between the current and proposed loss allocation provisions:

Assumptions:

- (i) Member A defaults on a business day (Day 1). On the same day, NSCC ceases to act for Member A and notifies Members of the cease to act. After liquidating Member A's portfolio and applying Member A's Clearing Fund deposit, NSCC has a loss of \$350 million.
- (ii) Member X voluntarily retires from membership five (5) business days after NSCC ceases to act for Member A (Day 6).
- (iii) Member B defaults seven (7) business days after NSCC ceases to act for Member A (Day 8). On the same day, NSCC ceases to act for Member B and notifies Members of the cease to act. After liquidating Member B's portfolio and applying Member B's Clearing Fund deposit, NSCC has a loss of \$350 million.
- (iv) The current NSCC loss provisions require NSCC to contribute no less than 25% of its retained earnings as a corporate contribution. For the purposes of this example, it is assumed that NSCC will contribute 25% of its retained earnings. The amount of NSCC's retained earnings is \$416 million.
- (v) NSCC's General Business Risk Capital Requirement is \$154 million. Current Loss Allocation:

Under the current loss allocation provisions, with respect to the losses arising out of Member A's default, NSCC will contribute \$104 million (\$416 million * 25%) from retained earnings and then allocate the remaining loss of \$246 million (\$350 million - \$104 million) to Members.

With respect to losses arising out of Member B's default, NSCC will contribute \$78 million ((\$416 million - \$104 million) * 25%) from retained earnings and then allocate the remaining loss of \$272 million (\$350 million - \$78 million) to Members. Because Member X voluntarily retired before NSCC ceased to act for Member B, Member X is not subject to loss allocation with respect to losses arising out of Member B's default.

Altogether, with respect to losses arising out of defaults of Member A and Member B, NSCC will contribute \$182 million of retained earnings and will allocate losses of \$518 million to Members.

Proposed Loss Allocation:

Under the proposed loss allocation provisions, a Defaulting Member Event with respect to Member A's default would have occurred on Day One, and a Defaulting Member Event with respect to Member B's default would have occurred on Day 8. Because the Defaulting Member Events occurred during a 10-business day period, they would be grouped together into an Event Period for purposes of allocating losses to Members. The Event Period would begin on the 1st business day and end on the 10th business day.

With respect to losses arising out of Member A's default, NSCC would apply a Corporate Contribution of \$77 million (\$154 million * 50%) and then allocate the remaining loss of \$273 million (\$350 million – \$77 million) to Members. With respect to losses arising out of Member B's default, NSCC would not apply a Corporate Contribution since it would have already contributed the maximum Corporate Contribution of 50% of its General Business Risk Capital Requirement. NSCC would allocate the losses of \$350 million arising out of Member B's default to Members. Because Member X was a Member on the first day of the Event Period, Member X would be subject to loss allocation with respect to all events occurring during the Event Period, even if the event occurred after its retirement. Therefore, Member X would be subject to loss allocation with respect to Member B's default.

Altogether, with respect to losses arising out of defaults of Member A and Member B, NSCC would apply a Corporate Contribution of \$77 million and would allocate losses of \$623 million to Members. The principal differences in the above example are

²⁸ For purposes of this example, NSCC has assumed that the losses occurred with guaranteed CNS activity of Members, and NSCC allocated all such Members' deposits to the Clearing Fund to CNS activity (which is typically more than 99% of the NSCC daily gross settlement amount).

due to (i) the proposed changes to the calculation and application of the Corporate Contribution and (ii) the proposed introduction of an Event Period.

(ii) Detailed Description of the Proposed Rule Changes Related to Loss Allocation

A. Proposed Changes to Rule 4 (Clearing Fund)

Overview of Rule 4 (Clearing Fund)

Rule 4 currently addresses Clearing Fund requirements and loss allocation obligations. While Procedure XV addresses the various Clearing Fund calculations, Rule 4 sets forth rights, obligations and other aspects associated with the Clearing Fund, as well as the loss allocation process. Rule 4 is currently organized into 12 sections. NSCC is proposing changes to each section, and consolidating provisions in Rule 4 relating to Mutual Fund Services and Insurance and Retirement Processing Services into new sections, as described below.

Section 1

Section 1 of Rule 4 currently sets forth the requirement that each Member and Mutual Fund/Insurance Services Member shall, and each Fund Member and Insurance Carrier/Retirement Services Member may, be required to make a deposit to the Clearing Fund. Section 1 currently provides that each participant's Required Deposit is based on one or more formulas specified by NSCC's Board of Directors. The basis of each such formula is participants' usage of NSCC's facilities. Section 1 also currently sets forth the minimum amount of each participant category's Required Deposit.

Current Section 1 allows a portion of a participant's Clearing Fund deposit to be evidenced by an open account indebtedness secured by Eligible Clearing Fund Securities, subject to certain limitations set forth in Procedure XV, and sets forth the various requirements associated with the deposit of Eligible Clearing Fund Securities. Current Section 1 also permits NSCC to require participants to post a letter of credit where NSCC believes the participants present legal risk.

Current Section 1 also provides that NSCC allocate the Clearing Fund by types of service (e.g., Mutual Fund Services) as well as by Systems (e.g., CNS), and divide the Clearing Fund into separate "Allocations" for each such service and separate "Funds" for each such System.

Under the proposed rule change, NSCC is proposing to add a subheading

of "Required Fund Deposits" to Section 1 and restructure Section 1 so that it applies to Members only and delete references to Mutual Fund/Insurance Services Members, Fund Members and Insurance Carrier/Retirement Services Members from Section 1.29 Provisions of Rule 4 regarding Mutual Fund/ Insurance Services Members and Fund Members would be covered in a new proposed Section 13 to Rule 4, discussed below. Provisions of Rule 4 regarding Insurance Carrier/Retirement Services Members would be covered in a new proposed Section 14 to Rule 4, discussed below.

Under the proposed rule change, Section 1 would continue to have the same provisions as they relate to Members except for the following: (i) The language throughout the section would be reorganized, streamlined and clarified, (ii) "Required Deposits" would be renamed "Required Fund Deposits," 30 which is a more descriptive term to refer to Members' deposits required for the Clearing Fund, and would harmonize with the rules of FICC/GSD and FICC/MBSD 31 and the term used in such rules,32 (iii) a sentence would be added regarding additional deposits maintained by the Members at NSCC, (iv) the provision regarding the Clearing Fund being allocated by Systems and services would be deleted,³³ and (v) change "Rules" to "Rules and Procedures" to better reflect the name of NSCC's rulebook.34

The proposed sentence regarding additional deposits to the Clearing Fund would permit Members to post such additional deposits at their discretion and would make clear that such additional deposits would be deemed to be part of the Clearing Fund and the Member's Actual Deposit (as discussed

below and as defined in the proposed rule change) but would not be deemed to be part of the Member's Required Fund Deposit.

NSCC proposes to add language in Section 1 to make it clear that each Member would grant NSCC a first priority perfected security interest in its right, title and interest in and to any Eligible Clearing Fund Securities, funds and assets pledged to NSCC to secure the Member's open account indebtedness or placed by the Member in NSCC's possession (or its agents acting on its behalf) to secure all such Member's obligations to NSCC, and that NSCC would be entitled to exercise the rights of a pledgee under common law and a secured party under Articles 8 and 9 of the New York Uniform Commercial Code with respect to such assets. The additional language would further harmonize the Rules with language used in the FICC/GSD Rules and FICC/MBSD Rules,³⁵ thus providing consistent treatment of pledged resources for firms that are members of both NSCC and FICC.

NSCC proposes to clarify the language in footnote 2 of Section 1. In addition, NSCC proposes to add "Eligible Letter of Credit" as a defined term to refer to letters of credit posted by participants if required by NSCC,³⁶ which would harmonize the term with the term used in the FICC/GSD Rules and FICC/MBSD Rules,³⁷ thus providing consistent terminology for firms that are members of both NSCC and FICC.

Similarly, NSCC proposes to add "Actual Deposit" as a defined term in Section 1 to refer to Eligible Clearing Fund Securities, funds and assets pledged to NSCC to secure a Member's open account indebtedness or placed by a Member in the possession of NSCC (or its agents acting on its behalf) and any Eligible Letters of Credit issued on behalf of a Member in favor of NSCC.

Instead of requiring participants to pledge Eligible Clearing Fund Securities to NSCC's account at a Qualified Securities Depository designated by the participants, NSCC proposes to clarify and streamline Section 1 of proposed Rule 4 to provide that Eligible Clearing Fund Securities pledged to secure a Member's open account indebtedness would be delivered to NSCC's account at DTC.

NSCC would delete the provision regarding allocation of the Clearing

²⁹ In addition to Section 1 of Rule 4, NSCC is proposing to delete references to Mutual Fund/Insurance Services Members, Fund Members and Insurance Carrier/Retirement Services Members from Sections 2, 3, 4, 5, 6, 7, 8, 9, and 12 of Rule

³⁰ In addition to Section 1 of Rule 4, NSCC is proposing to rename "Required Deposits" to "Required Fund Deposits" in Sections 2, 3, 4, 8, 9, and 11 of Rule 4.

³¹ FICC/GSD Rulebook ("FICC/GSD Rules"), available at http://dtcc.com/~/media/Files/ Downloads/legal/rules/ficc_gov_rules.pdf and FICC/ MBSD Clearing Rules ("FICC/MBSD Rules"), available at http://dtcc.com/~/media/Files/ Downloads/legal/rules/ficc_mbsd_rules.pdf.

³² See FICC/GSD Rule 1 (Definitions) and FICC/MBSD Rule 1 (Definitions), supra note 31.

³³ In addition to Section 1 of Rule 4, NSCC is proposing to delete references to the Clearing Fund being allocated by Systems and services from Sections 2, 3, and 4 of Rule 4.

³⁴In addition to Section 1 of Rule 4, NSCC is proposing to change "Rules" to "Rules and Procedures" in Sections 9 and 12 of Rule 4.

 $^{^{35}}$ See Section 4 of FICC/GSD Rule 4 and Section 4 of FICC/MBSD Rule 4, supra note 31.

 $^{^{36}}$ In addition to Section 1 of Rule 4, NSCC is also proposing to rename "Letter of Credit" to "Eligible Letter of Credit" in Sections 2 and 12 of Rule 4.

³⁷ See FICC/GSD Rule 1 (Definitions) and FICC/MBSD Rule 1 (Definitions), supra note 31.

Fund by Systems and services, as this provision is no longer relevant under the proposed rule change. Provisions relating to Mutual Fund Services and Insurance and Retirement Processing Services in Section 1 (as well as other sections in Rule 4) would be consolidated in the proposed new Sections 13 and 14, entitled "Mutual Fund Deposits" and "Insurance Deposits," respectively.

To consolidate provisions regarding the maintenance, investment and permitted use of Clearing Fund, NSCC would move the last paragraph of Section 1 about segregation and maintenance of Clearing Fund (again, in terms of "Fund," "System," and "Allocation," as discussed above) to Section 2.

In addition, NSCC proposes to correct a typographical error in the reference to a footnote in Section 1 of Rule 4. Specifically, there is an incorrect reference to footnote 22 in the second paragraph of Section 1 in current Rule 4. NSCC is proposing to change this reference to reflect the correct footnote, which is footnote 2.

Section 2

Section 2 of Rule 4 currently covers the permitted uses of the Clearing Fund (again by "Fund" and "Allocation," as set forth in current Section 1), including the investment of Clearing Fund Cash and Cash Receipts, as well as participants' rights to any interest earned or paid on pledged Eligible Clearing Fund Securities or cash deposits.

NSCC is proposing to add a subheading of "Permitted Use, Investment, and Maintenance of Clearing Fund Assets" to Section 2 and restructure Section 2 so that it applies to Members only. NSCC is also proposing to restructure Section 2 so that the permitted use of Clearing Fund appears first, then the investment of Clearing Fund, followed by maintenance of Clearing Fund.

Under the proposed rule change, the permitted use of Clearing Fund paragraph would continue to have the same provisions as they relate to how the Clearing Fund can be used by NSCC, except the provisions would be streamlined and clarified. Specifically, in order to be consistent with the proposed change in Section 4 (as described below) regarding NSCC requiring Members to pay their loss allocation amounts (leaving their Required Fund Deposits intact), NSCC is proposing to modify the permitted use of Clearing Fund to make it clear that the Clearing Fund can be used by NSCC to secure each Member's performance of

obligations to NSCC, including each Member's obligations with respect to any loss allocations as set forth in Section 4 of Rule 4. NSCC is also proposing to delete the defined term of Cash Receipts and related provisions from Rule 4 because, unlike the Clearing Fund, Cash Receipts are money payments received from participants and payable to others; therefore, NSCC believes that continuing to include Cash Receipts in Rule 4 is no longer necessary and may cause confusion among Members.

NSCC is proposing to add a paragraph that provides that each time NSCC uses any part of the Clearing Fund to provide liquidity to NSCC to meet its settlement obligations, including, without limitation, through the direct use of cash in the Clearing Fund or through the pledge or rehypothecation of pledged Eligible Clearing Fund Securities in order to secure liquidity for more than thirty (30) calendar days, NSCC, at the close of business on the 30th calendar day (or on the first business day thereafter) from the day of such use, would consider the amount used but not yet repaid as a loss to the Clearing Fund incurred as a result of a Defaulting Member Event and immediately allocate such loss in accordance with proposed Section 4 of Rule 4. NSCC believes that this proposed change would increase transparency and accessibility of the Rules for Members by specifying a point in time by which NSCC would need to replenish the Clearing Fund through loss allocation if NSCC uses the Clearing Fund to provide or secure liquidity to NSCC to meet its settlement obligations. NSCC believes that a period of thirty (30) calendar days would be appropriate because it would provide sufficient time for NSCC to determine whether it would be able to obtain the necessary funds from liquidation of the portfolio of the Defaulting Member to repay the used Clearing Fund amount. In addition, this proposed change would also harmonize this section with the comparable section in the FICC/GSD Rules and FICC/MBSD Rules,³⁸ so as to provide consistent treatment for firms that are members of both NSCC and FICC.

Proposed Section 2 would continue to have the same provisions concerning the investment and maintenance of the Clearing Fund, except these provisions would also be streamlined and clarified. Specifically, NSCC is proposing language to make it clear that it may invest cash in the Clearing Fund in accordance with the Clearing Agency

Investment Policy adopted by NSCC.39 NSCC would revise the relocated sentence from Section 1 which provides that NSCC shall not be required to segregate any Clearing Fund (again, in terms of "Fund," "System," and "Allocation," as discussed above) in order to (i) conform to the proposed deletions in Section 1 and use the newly defined term of "Actual Deposit" as set forth in Section 1 and (ii) make clear that NSCC would not be required to segregate a Member's Actual Deposit but that NSCC would maintain books and records concerning the assets that constitute each Member's Actual Deposit.

Under the proposed rule change,
Members would continue to be entitled
to any interest earned or paid on
Clearing Fund cash deposits and
pledged Eligible Clearing Fund
Securities; however, NSCC is proposing
additional language to make it clear that
interest on pledged Eligible Clearing
Fund Securities that is received by
NSCC would be credited to a Member's
cash deposits to the Clearing Fund,
except in the event of a default by such
Member on any obligations to NSCC, in
which case NSCC may exercise its rights
under proposed Section 3 of Rule 4.

Section 3

Section 3 of Rule 4 currently provides that NSCC may apply a participant's actual deposit to any obligation the participant has to NSCC that the participant has failed to satisfy and to any Cross-Guaranty Obligation. Participants are required to eliminate any resulting deficiencies in their Required Deposits within such time as NSCC requires. Section 3 also currently provides for the manner in which loss allocation would apply with respect to Off-the-Market Transactions.

 $^{^{38}}$ See Section 5 of FICC/GSD Rule 4 and Section 5 of FICC/MBSD Rule 4, supra note 31.

³⁹ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-NSCC-2016-003). The Clearing Agency Investment Policy (the "Policy") governs the management, custody, and investment of cash deposited to the Clearing Fund, the proprietary liquid net assets (cash and cash equivalents) of NSCC and other funds held by NSCC. The Policy sets forth guiding principles for the investment of those funds, which include adherence to a conservative investment philosophy that places the highest priority on maximizing liquidity and avoiding risk, as well as mandating the segregation and separation of funds. The Policy also addresses the process for evaluating credit ratings of counterparties and identifies permitted investments within specified parameters. In general, assets are required to be held by regulated and creditworthy financial institution counterparties and invested in financial instruments that, with respect to the Clearing Fund, may include deposits with banks, including the Federal Reserve Bank of New York collateralized reverse-repurchase agreements, direct obligations of the U.S. government and money market mutual funds

Under the proposed rule change, NSCC is proposing to add a subheading of "Application of Clearing Fund Deposits and Other Amounts to Members' Obligations'' and to delete provisions that do not apply to Members and/or that reference the Clearing Fund being allocated into Funds/Allocations by Systems and services. Under the proposed rule change, NSCC would retain the provisions in Section 3 regarding applying the Member's Actual Deposit to satisfy an obligation to NSCC that a Member fails to satisfy and the requirement to replenish the Required Fund Deposit as necessary, but NSCC proposes to add clarifying language that, in addition to a Member's Actual Deposit, NSCC will also apply any amounts available under a Clearing Agency Cross-Guaranty Agreement and any proceeds therefrom to satisfy the obligation. NSCC also proposes to add language making it clear that NSCC may take any and all actions with respect to the assets and amounts referenced in the prior sentence, including assignment, transfer, and sale of any Eligible Clearing Fund Securities, that NSCC determines is appropriate.

Under the proposed rule change, NSCC would move the provision regarding allocation of losses from Off-the-Market Transactions to proposed Section 4 of Rule 4, which addresses allocation of losses to Members. NSCC would streamline and clarify the remaining provisions for transparency and accessibility.

Section 4 and Section 5

Current Section 4 of Rule 4 contains NSCC's current loss allocation waterfall, which would be initiated if NSCC incurs a loss or liability in a System that is not satisfied pursuant to current Section 3. Section 4 currently provides for the following loss allocation waterfall:

- (i) Application of NSCC's existing retained earnings or such lesser part ⁴⁰ of the existing retained earnings unless the Board of Directors elects to apply the Fund/Allocation for a particular System or service.
- (ii) If a loss or liability remains after the application of the retained earnings, NSCC would apply the Clearing Fund (this application is subject to the current structure where the Rules provide that the Clearing Fund is allocated to different Systems/services).

a. NSCC is required to provide participants and the Commission with 5 business days' prior notice before applying the Clearing Fund.

b. Participants (other than those responsible for causing the loss or liability) would be charged pro rata based upon their allocation to the applicable Fund, less any amounts that participants were required to deposit pursuant to Rule 15.

Section 5 of Rule 4 currently states that if a pro rata charge is made pursuant to Rule 4 against a participant's actual Clearing Fund deposit, and as a consequence thereof the participant's remaining deposit is less than its Required Deposit, the participant would, upon demand by NSCC, be required to replenish its deposit to eliminate the deficiency within such time as NSCC shall require. Current Section 5 further provides that if the participant does not take this required action, NSCC may take disciplinary action against the participant, and any disciplinary action taken against the participant or the voluntary or involuntary termination of the participant's membership will not affect the obligations of the participant to NSCC or any remedy to which NSCC may be entitled under applicable law.

Under the proposed rule change, NSCC is proposing to add a subheading of "Loss Allocation Waterfall, Off-the-Market Transactions" to Section 4 and delete provisions that do not apply to Members and/or that reference the Clearing Fund being allocated into Funds/Allocations by System or service. In addition, NSCC is proposing to restructure its loss allocation waterfall as described below.

Under the proposal, Section 4 would make clear that the loss allocation waterfall applies to any loss and liability incurred by NSCC arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event.

As proposed, Section 4 would provide that, for the purposes of Rule 4, the term "Defaulting Member" would mean a Member for which NSCC has ceased to act pursuant to Rule 46,41 the term "Defaulting Member Event" would mean the determination by NSCC to cease to act for a Member pursuant to Rule 46, and the term "Declared Non-Default Loss Event" would mean the determination by the Board of Directors that a loss or liability incident to the clearance and settlement business of

NSCC may be a significant and substantial loss or liability that may materially impair the ability of NSCC to provide clearance and settlement services in an orderly manner and will potentially generate losses to be mutualized among Members in order to ensure that NSCC may continue to offer clearance and settlement services in an orderly manner. Proposed Section 4 would establish the concept of an "Event Period" to provide for a clear and transparent way of handling multiple loss events occurring in a period of ten (10) business days, which would be grouped into an Event Period.⁴² As stated above, both Defaulting Member Events or Declared Non-Default Loss Events could occur within the same Event Period.

Under the proposal, an Event Period with respect to a Defaulting Member Event would begin on the day NSCC notifies participants that it has ceased to act for the Defaulting Member (or the next business day, if such day is not a business day). In the case of a Declared Non-Default Loss Event, an Event Period would begin on the day that NSCC notifies Members of the Declared Non-Default Loss Event (or the next business day, if such day is not a business day). If a subsequent Defaulting Member Event or Declared Non-Default Loss Event occurs during an Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period.

As proposed, each Member would be obligated to NSCC for the entire amount of any loss or liability incurred by NSCC arising out of or relating to any Defaulting Member Event with respect to such Member. Under the proposal, to the extent that such loss or liability is not satisfied pursuant to proposed Section 3 of Rule 4, NSCC would apply a Corporate Contribution thereto and charge the remaining amount of such loss or liability ratably to other Members, as provided in proposed Section 4.

Under proposed Section 4, the loss allocation waterfall would begin with a corporate contribution from NSCC ("Corporate Contribution"), as is the case under the current Rules, but in a different form than under the current Section 4 of Rule 4. Today, pursuant to Addendum E, in the event of a Member impairment, NSCC is required to apply at least 25% of its retained earnings existing at the time of a Member impairment; however, no corporate

⁴⁰ Addendum E provides that NSCC "will apply no less than twenty-five percent (25%) of its retained earnings, existing at the time of a Member impairment which gives rise to a loss or liability not satisfied by the impaired Member's Clearing Fund deposit, to such loss or liability." *Supra* note 5.

⁴¹NSCC may cease to act for a Member pursuant to any of the circumstances set forth under Rule 46 (Restrictions on Access to Services), including, but not limited to, in the event the Member is in default of any delivery of funds or securities to NSCC. Supra note 5.

⁴² Supra note 15.

contribution from NSCC is currently required for losses resulting other than those from Member impairments. Under the proposal, NSCC would amend Section 5 to add a subheading of "Corporate Contribution" and define NSCC's Corporate Contribution with respect to any loss allocation pursuant to proposed Section 4 of Rule 4, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, as an amount that is equal to fifty (50) percent of the amount calculated by NSCC in respect of its General Business Risk Capital Requirement as of the end of the calendar quarter immediately preceding the Event Period.⁴³ The proposed rule change would specify that NSCC's General Business Risk Capital Requirement, as defined in NSCC's Clearing Agency Policy on Capital Requirements,44 is, at a minimum, equal to the regulatory capital that NSCC is required to maintain in compliance with

Rule 17Ad–22(e)(15) under the Act.⁴⁵ As proposed, if NSCC applies the Corporate Contribution to a loss or liability arising out of or relating to one or more Defaulting Member Events or Declared Non-Default Loss Events relating to an Event Period, then for any subsequent Event Periods that occur during the two hundred fifty (250) business days thereafter,46 the Corporate Contribution would be reduced to the remaining unused portion of the Corporate Contribution amount that was applied for the first Event Period. Proposed Section 5 would require NSCC to notify Members of any such reduction to the Corporate Contribution.

Currently, the Rules do not require NSCC to contribute its retained earnings to losses and liabilities other than from Member impairments. Under the proposal, NSCC would expand the application of its corporate contribution beyond losses and liabilities from Member impairments. The proposed Corporate Contribution would apply to losses or liabilities relating to or arising out of Defaulting Member Events and Declared Non-Default Loss Events, and would be a mandatory loss contribution by NSCC prior to any allocation of the loss among Members.

Addendum E currently provides NSCC the option to contribute amounts higher than the specified percentage of retained earnings, as determined by the Board of Directors, to any loss or liability incurred by NSCC as the result of a Member's impairment. This option

 43 Supra note 8.

would be retained and expanded under the proposal to also cover non-default losses. Proposed Section 5 would provide that nothing in the Rules would prevent NSCC from voluntarily applying amounts greater than the Corporate Contribution against any NSCC loss or liability, whether arising out of or relating to a Defaulting Member Event or a Declared Non-Default Loss Event, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation existing at the time.

Proposed Section 4 of Rule 4 would provide that NSCC shall apply the Corporate Contribution to losses and liabilities that arise out of or relate to one or more Defaulting Member Events and/or Declared Non-Default Loss Events that occur within an Event Period. The proposed rule change also provides that if losses and liabilities with respect to such Event Period remain unsatisfied following application of the Corporate Contribution, NSCC would allocate such losses and liabilities to Members, as described below.

Proposed Section 4 of Rule 4 would also retain the requirement of loss allocation among Members if a loss or liability remains after the application of the Corporate Contribution, as described above. In contrast to the current Section 4 where NSCC would apply Members' Required Deposits to the mutualized loss allocation amounts, under the proposal, NSCC would require Members to pay their loss allocation amounts (leaving their Required Fund Deposits intact).47 Loss allocation obligations would continue to be calculated based upon a Member's pro rata share of losses and liabilities (although the pro rata share would be calculated differently than it is today), and Members would

still retain the ability to voluntarily withdraw from membership and cap their loss allocation obligation (although the loss allocation obligation would also be calculated differently than it is today).

The proposed rule change to Section 4 of Rule 4 would clarify that each Member that is a Member on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Defaulting Member Event (other than a Defaulting Member Event with respect to which it is the Defaulting Member) and each Declared Non-Default Loss Event occurring during the Event Period. The proposal would make it clear that any Member for which NSCC ceases to act on a nonbusiness day, triggering an Event Period that commences on the next business day, shall be deemed to be a Member on the first day of that Event Period.

Under the proposed rule change, a loss allocation "round" would mean a series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the round cap. When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. NSCC may continue the loss allocation process in successive rounds until all losses from the Event Period are allocated among Members that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 6 of

As proposed, each loss allocation would be communicated to Members by the issuance of a Loss Allocation Notice. Under the proposal, each Member's pro rata share of losses and liabilities to be allocated in any round would be equal to (i) the Member's Average RFD divided by (ii) the sum of Average RFD amounts of all Members subject to loss allocation in such round.

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Member in that round has five (5) business days from the issuance of such first Loss Allocation Notice for the round (such period, a "Loss Allocation Withdrawal Notification Period") to notify NSCC of its election to withdraw from membership with NSCC pursuant to

⁴⁴ Supra note 9.

⁴⁵ Supra note 10.

⁴⁶ Supra note 13.

 $^{^{\}rm 47}\,\rm NSCC$ believes that shifting from the two-step methodology of applying the Clearing Fund and then requiring Members to immediately replenish it, to requiring direct payment would increase efficiency while preserving the right to charge a Member's Clearing Fund deposits in the event the Member does not timely pay. Such a failure to pay would trigger recourse to the Clearing Fund deposits of the Member under proposed Section 3 of Rule 4. In addition, this change would provide greater stability for NSCC in times of stress by allowing NSCC to retain the Clearing Fund, its critical prefunded resource, while charging loss allocations. NSCC believes doing so would allow NSCC to cover its current credit exposures to Members at all times. By retaining the Clearing Fund as proposed, NSCC could use the Clearing Fund to secure the performance obligations of Members to NSCC, including their payment obligation for any loss allocation, while maintaining access to prefunded resources. By being able to manage its current credit exposures throughout the loss allocation process, NSCC would be able to continue to provide its critical operations and services during what would be expected to be a stressful period.

proposed Section 6 of Rule 4, and thereby benefit from its Loss Allocation Cap. 48 As proposed, the "Loss Allocation Cap" of a Member would be equal to the greater of (x) its Required Fund Deposit on the first day of the applicable Event Period and (y) its Average RFD.

NSCC is proposing to clarify that after a first round of loss allocation with respect to an Event Period, only Members that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 6 of Rule 4 would be subject to further loss allocation with respect to that Event Period.

As proposed, Members would have two (2) business days after NSCC issues a first round Loss Allocation Notice to pay the amount specified in any such notice.⁴⁹ On a subsequent round (*i.e.,* if the first round did not cover the entire loss of the Event Period because NSCC was only able to allocate up to the round cap), Members would also have two (2) business days after notice by NSCC to pay their loss allocation amounts (again subject to their Loss Allocation Caps), unless Members have notified (or will timely notify) NSCC of their election to withdraw from membership with respect to a prior loss allocation round pursuant to proposed Section 6 of Rule 4.

As proposed, Section 4 would also provide that, to the extent that a Member's Loss Allocation Cap exceeds the Member's Required Fund Deposit on the first day of the applicable Event Period, NSCC may in its discretion retain any excess amounts on deposit from the Member, up to the Member's Loss Allocation Cap.

Under the proposal, if a Member fails to make its required payment in respect of a Loss Allocation Notice by the time such payment is due, NSCC would have the right to proceed against such Member as a Member that has failed to satisfy an obligation in accordance with proposed Section 3 of Rule 4 described above. Members who wish to withdraw would be required to comply with the requirements in proposed Section 6 of Rule 4, described further below. Specifically, proposed Section 4 of Rule 4 would provide that if, after notifying NSCC of its election to withdraw from membership pursuant to proposed Section 6 of Rule 4, the Member fails to comply with the provisions of proposed Section 6 of Rule 4, its notice of withdrawal would be deemed void and any further losses resulting from the applicable Event Period may be

allocated against it as if it had not given such notice.

Under the proposal, NSCC would delete the provision in current Section 4 of Rule 4 that requires NSCC to provide Members and the Commission with 5 business days' prior notice before applying the Clearing Fund to a loss or liability because such requirement would no longer be relevant under the proposed rule change. Under the proposed rule change, NSCC would notify Members subject to loss allocation of the amounts being allocated to them in one or more Loss Allocation Notices. As proposed, instead of applying the Clearing Fund, NSCC would require Members to pay their loss allocation amounts (leaving their Clearing Fund deposits intact). In order to conform to these proposed rule changes, NSCC is proposing to eliminate the required notification to Members regarding the application of Clearing Fund in current Section 4 of Rule 4. NSCC is also proposing to delete the required notification to the Commission regarding the application of Clearing Fund in the same section. While as a practical matter, NSCC would notify the Commission of a decision to loss allocate, NSCC does not believe such notification needs to be specified in the Rules.

Under the proposed rule change, NSCC would move the provision related to Off-the-Market Transactions from current Section 3 of Rule 4 to proposed Section 4 of Rule 4 and clarify that (i) a loss or liability of NSCC in connection with the close-out or liquidation of an Off-the-Market Transaction would be allocated to the Member that was the counterparty to such transaction and (ii) no allocation would be made if the Defaulting Member satisfied all applicable intraday mark-to-market margin charges assessed by NSCC with respect to the Off-the-Market Transaction prior to its default.50

Section 6

Proposed Section 6 of Rule 4 would include the provisions regarding withdrawal from membership currently covered by Section 8 of Rule 4. NSCC believes that relocating the provisions on withdrawal from membership as it pertains to loss allocation, so that it comes right after the section on the loss allocation waterfall, would provide for the better organization of Rule 4. As proposed, the subheading for Section 6

would read "Withdrawal Following Loss Allocation."

Currently, Section 8 of Rule 4 provides that participants may notify NSCC within ten (10) business days after receipt of notice of a pro rata charge that they have elected to terminate their membership and thereby avail themselves of a cap on loss allocation, which is currently their Required Deposit as fixed immediately prior to the time of the pro rata charge.

As stated above, under the proposed rule change, a Member who wishes to withdraw from membership in respect of a loss allocation round must provide notice of its election to withdraw ("Loss Allocation Withdrawal Notice") within five (5) business days from the issuance of the first Loss Allocation Notice in any round.⁵¹ In order to avail itself of its Loss Allocation Cap, the Member would need to follow the requirements in proposed Section 6 of Rule 4, which would provide that the Member must: (i) Specify in its Loss Allocation Withdrawal Notice an effective date for withdrawal from membership, which date shall not be later than ten (10) business days following the last day of the Loss Allocation Withdrawal Notification Period (i.e., no later than ten (10) business days after the 5th business day following the first Loss Allocation Notice in that round of loss allocation),52 (ii) cease all activity that would result in transactions being submitted to NSCC for clearance and settlement for which such Member would be obligated to perform, where the scheduled final settlement date would be later than the effective date of the Member's withdrawal, and (iii) ensure that all clearance and settlement activity for which such Member is obligated to NSCC is fully and finally settled by the effective date of the Member's withdrawal, including, without limitation, by resolving by such date all fails and buy-in obligations.

Proposed Section 6 of Rule 4 would provide that a Member that withdraws in compliance with the requirements of proposed Section 6 of Rule 4 would nevertheless remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under proposed Rule 4; however, the Member's aggregate obligation would be limited to the amount of its Loss Allocation Cap (as fixed in the round for which it withdrew).

NSCC is proposing to include a sentence in proposed Section 6 of Rule 4 to make it clear that if the Member

⁴⁸ Supra note 18.

 $^{^{49}}$ Supra note 22.

⁵⁰ See Securities Exchange Act Release No. 79598 (December 19, 2016), 81 FR 94462 (December 23, 2016) (SR-NSCC-2016-005), at 94465, and Securities Exchange Act Release No. 79592 (December 19, 2016), 81 FR 94448 (December 23, 2016) (SR-NSCC-2016-803), at 94452.

⁵¹ Supra note 18.

⁵² Supra note 25.

fails to comply with the requirements set forth in that section, its Loss Allocation Withdrawal Notice will be deemed void, and the Member will remain subject to further loss allocations pursuant to proposed Section 4 of Rule 4 as if it had not given such notice.

Currently, Section 8 also contains provisions regarding additional pro rata charges that may be made by NSCC for the same loss or liability under the existing loss allocation process and the applicable caps that participants wishing to voluntarily terminate their membership after such additional pro rata charges are noticed may avail themselves of. These provisions would be replaced by the loss allocation process contained in proposed Section 4 described above.

Section 7

As proposed, Section 7 would cover the provisions on the return of a Member's Clearing Fund deposit that are currently covered by Section 6 of Rule 4. Proposed Section 7's subheading would be "Return of Members' Clearing Fund Deposits" and would apply only to Members.

Currently, with respect to the return of Clearing Fund deposits, Section 6 of Rule 4 states that NSCC will return a participant's Clearing Fund deposit 90 days after 3 conditions are met: (i) The participant ceases to be a participant, (ii) all transactions open at the time the participant ceases to be a participant which could result in a charge to the Clearing Fund have been closed, and (iii) all obligations of the participant to NSCC have been satisfied or have been deducted from the participant's Clearing Fund deposit by NSCC, provided that the participant has provided NSCC with satisfactory indemnities or guarantees or another participant has been substituted on all transactions and obligations of the participant.

Current Section 6 provides further that in the absence of an acceptable guarantee, indemnity or substitution, NSCC will retain the entire Clearing Fund deposit of a participant if such deposit is less than \$100,000 for two (2) years (or four (4) years for Members who have Sponsored Accounts at a Qualified Securities Depository) after conditions described in (i), (ii) and (iii) of the paragraph above have occurred. If the participant's Clearing Fund deposit is equal to or greater than \$100,000, NSCC will retain the greater of twenty-five (25) percent of a participant's average Clearing Fund requirement over the twelve (12) months immediately prior to the date the participant ceased to be a participant, or \$100,000 for two (2) years (or four (4) years for Members who

have Sponsored Accounts at a Qualified Securities Depository) after conditions described in (i), (ii) and (iii) of the paragraph above have occurred.

Current Section 6 states that if a participant made a deposit with respect to the Mutual Fund Services or Insurance and Retirement Processing Services, the participant will be entitled to the return of this deposit ninety (90) days after all associated transactions in these services have been satisfied.

Finally, Section 6 currently provides that any obligation of a participant to NSCC unsatisfied at the time the participant ceases to be a participant will not be affected by such cessation of membership.

Proposed Section 7 would reduce the period in which NSCC may retain a Member's Clearing Fund deposit. Specifically, NSCC proposes that if a Member gives notice to NSCC of its election to withdraw from membership, NSCC will return the Member's Actual Deposit in the form of (i) cash or securities within thirty (30) calendar days and (ii) Eligible Letters of Credit within ninety (90) calendar days, after all of the Member's transactions have settled and all matured and contingent obligations to NSCC for which the Member was responsible while a Member have been satisfied, except NSCC may retain for up to two (2) years the Actual Deposits from Members who have Sponsored Accounts at DTC. NSCC believes that shortening the time periods for the return of a Member's Clearing Fund deposit would be helpful to firms who have exited NSCC so that they could have use of the deposits sooner than under the current Rules. while at the same time protecting NSCC because such return would only occur if all obligations of the terminating Member to NSCC have been satisfied. Proposed Section 7 would also harmonize the retention period for a Member's deposits to the Clearing Fund with the FICC/GSD Rules,53 thus providing consistent treatment for firms that are members of both NSCC and FICC. Similarly, the Clearing Fund deposit retention for Members who have Sponsored Accounts at DTC would be reduced in order to stay consistent with

the proposed retention period in the rules of DTC.⁵⁴ In addition, NSCC proposes to make it clear that a Member's obligations to NSCC would include both matured as well as contingent obligations.

Section 8

Proposed Section 8 of Rule 4 would cover the subject matter currently covered in Section 7 of Rule 4. Proposed Section 8's subheading would be "Changes in Members' Required Fund Deposits" and would apply only to Members.

Currently, Section 7 of Rule 4 requires participants to satisfy any increase in their Required Deposit within such time as NSCC requires. At the time the increase becomes effective, the participant's obligations to NSCC will be determined in accordance with the increased Required Deposit whether or not the Member has so increased its deposit. NSCC is not proposing any substantive changes to this provision, which will be renumbered as Section 8 of Rule 4 under the proposed rule change, except for streamlining the provision and limiting its application to Members as stated above.

Section 9

Currently, Section 9 of Rule 4 addresses situations where a participant has excess deposits in the Clearing Fund (i.e., amounts above its Required Deposit). The current provision provides that NSCC will, on any day that NSCC has determined and provided notification that an excess deposit exists with respect to a participant, return an excess amount requested by a participant that follows the formats and timeframe established by NSCC for such request. The current provision makes clear that NSCC will not return the requested excess amount (i) until any amount required to be charged against the participant's Required Deposit is paid by the participant to NSCC and/or (ii) if NSCC determines that the participant's current month's use of one or more services is materially different than the previous month's use upon which such excess is based. Section 9 currently makes clear that, notwithstanding any of the foregoing,

⁵³ Section 10 of FICC/GSD Rule 4, in relevant part, states that "If a Netting Member gives notice to the Corporation pursuant to Rule 3 of its election to terminate its membership in the Netting System, the Member's deposits to the Clearing Fund in the form of cash or securities shall be returned to it within 30 calendar days thereafter . . . provided that all amounts owing to the Corporation by the Member have been paid to the Corporation prior to such return and the Member has no remaining open Net Settlement Position, Fail Net Settlement Position, or Forward Net Settlement Position." Supra note 31.

⁵⁴ On December 18, 2017, DTC submitted a proposed rule change and an advance notice to enhance its rules regarding allocation of losses. See Securities Exchange Act Release Nos. 82426 (January 2, 2018), 83 FR 913 (January 8, 2018) (SR–DTC–2017–022) and 82582 (January 24, 2018), 83 FR 4297 (January 30, 2018) (SR–DTC–2017–804). On June 28, 2018, DTC submitted amendments to the proposed rule change and advance notice. Copies of the amendments to the proposed rule change and the advance notice are available at http://www.dtcc.com/legal/sec-rule-filings.aspx.

NSCC may, in its discretion, withhold any or all of a participant's excess deposit if the participant has been placed on the Watch List.⁵⁵ Current Section 9 also makes clear that nothing in this section limits NSCC's rights under Rule 15.⁵⁶

Proposed Section 9 would add a subheading "Excess Clearing Fund Deposits" and would apply only to Members. NSCC is not proposing any substantive changes to this provision, except for streamlining the provisions in this section and eliminating the condition described in clause (i) of the paragraph above that limits participants' ability to request the return of excess amounts on deposit in the Clearing Fund and replacing clause (ii) of the paragraph above with a clause that provides NSCC may, in its discretion, withhold any or all of a participant's excess deposit if NSCC determines that the Member's anticipated activities in NSCC in the near future may reasonably be expected to be materially different than its activities of the recent past. NSCC believes that the proposed additional clause would protect NSCC and its participants because the clause would allow NSCC to retain excess deposits to cover an expected near-term increase in a Member's Required Fund Deposit amount due to the anticipated change in the Member's activities. The proposed additional clause would also align NSCC's Rules with that of FICC/ GSD and FICC/MBSD,57 thus providing consistent treatment for firms that are members of both NSCC and FICC.

Section 10

Current Section 10 of Rule 4 provides for crediting persons against whom losses are charged pursuant to Rule 4 if there is a subsequent recovery of such losses by NSCC. NSCC is not proposing any changes to this section other than (i) making it clear that no loss allocation under proposed Rule 4 would constitute a waiver of any claim NSCC may have against a Member for any losses or liabilities to which the Member is subject under the Rules, including, without limitation, any loss or liability

to which it may be subject under proposed Rule 4, and (ii) adding a subheading "No Waiver; Subsequent Recovery Against Loss Amounts" and replacing "persons" with "Persons," which is currently defined in Rule 1 (Definitions and Descriptions) to mean 'a partnership, corporation, limited liability corporation or other organization, entity or an individual." NSCC is proposing the change in (i) above to preserve its legal rights and to make it clear to Members that loss allocation under proposed Rule 4 would not be deemed as NSCC waiving any claims it may have against a Member for any losses or liabilities to which the Member is subject under the Rules. With respect to the proposed change in (ii) above, given that NSCC is a corporation, NSCC believes that the term "Person" already includes NSCC; however, for increased clarity, NSCC is proposing to add "including the Corporation" to make it clear to Members that if there is a subsequent recovery of losses charged pursuant to Rule 4, the net amount of the recovery would be credited to Persons, including NSCC, against whom the loss was charged in proportion to the amounts charged against them.

Section 11

Current Section 11 of Rule 4 provides that a participant may withdraw Eligible Clearing Fund Securities from pledge, provided that the participant has deposited cash with, or pledged additional Eligible Clearing Fund Securities to, NSCC that, in the aggregate, secure the open account indebtedness of the participant and/or satisfy the participant's Required Deposit. Proposed Section 11 would add a subheading "Substitution or Withdrawal of Pledged Securities" and would apply only to Members. NSCC is not proposing any substantive changes to this provision, except for changes to improve the transparency and accessibility of this section.

Section 12

Current Section 12 of Rule 4 makes it clear that NSCC has certain rights with respect to the Clearing Fund. Proposed Section 12 would add a subheading "Authority of Corporation" and would apply only to Members. NSCC is not proposing any substantive changes to this provision, except to clarify that a reference to 30 days in current Section 12 would mean 30 calendar days.

Section 13

NSCC is proposing to add a new Section 13 to Rule 4 that would be entitled "Mutual Fund Deposits." Under

the proposal, NSCC would consolidate provisions from various sections in the current Rule 4 concerning Mutual Fund/ Insurance Services Members and Fund Members and group them into proposed Section 13. Aside from the consolidation, NSCC is not proposing any substantive changes to these provisions, except for changes to (i) reduce NSCC's retention period of Mutual Fund Deposits when a Mutual Fund Participant (as defined below and in the proposed rule change) elects to withdraw from membership, in order to harmonize it with the proposed change in Section 7, as described above, and (ii) improve the transparency and accessibility of the provisions.

Proposed Section 13 would provide that each Member that uses the Mutual Fund Services to submit mutual fund purchases, redemptions, or exchanges to any Fund Member or another Member and each Mutual Fund/Insurance Services Member would, and each Fund Member (collectively with such Members and Mutual Fund/Insurance Services Members, "Mutual Fund Participants") may, be required to make a cash deposit to the Clearing Fund in the amounts determined in accordance with Procedure XV and other applicable Rules (its "Mutual Fund Deposit" and, unless specified otherwise, for the purposes of the Rules, Required Fund Deposits shall include Mutual Fund Deposits). In the case of a Member, its Mutual Fund Deposit would be a separate and additional component of such Member's deposit to the Clearing Fund but not part of the Member's Required Fund Deposit for purposes of calculating pro rata loss allocations pursuant to proposed Section 4 of Rule

As in the current Rules, proposed Section 13 would also provide that if any Mutual Fund Participant fails to satisfy any obligation to NSCC relating to Mutual Fund Services, notwithstanding NSCC's right to reverse in whole or in part any credit previously given to the contra side to any outstanding Mutual Fund Services transaction of the Mutual Fund/ Insurance Services Member, NSCC would first apply such Mutual Fund Participant's Mutual Fund Deposit. If after such application any loss or liability remains and if such Mutual Fund Participant is a Member that is not otherwise obligated to NSCC, NSCC would apply such Member's Actual Deposit in accordance with proposed Section 3 of Rule 4. NSCC would next allocate any further remaining loss or liability to the other Mutual Fund Participants in successive rounds of loss allocations in each case up to the

⁵⁵ Pursuant to Section 4 of Rule 2B, a Member could be placed on the Watch List either based on its credit rating of 5, 6 or 7, which can either be generated by the Credit Risk Rating Matrix or from a manual downgrade, or when NSCC deems such placement as necessary to protect NSCC and its Members. *Supra* note 5.

⁵⁶ Rule 15 permits NSCC to require a Member, Limited Member or any applicant to become either to furnish NSCC adequate assurances of the entity's financial responsibility and operational capability as NSCC may deem necessary. Supra note 5.

⁵⁷ See Section 9 of FICC/GSD Rule 4 (Clearing Fund and Loss Allocation) and Section 9 of FICC/ MBSD Rule 4 (Clearing Fund and Loss Allocation). Supra note 31.

aggregate of Mutual Fund Deposits from non-defaulting Mutual Fund Participants, and after the first such round, Mutual Fund Participants that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 6 of Rule 4, following the procedures and timeframes set forth in proposed Sections 4 and 6 of Rule 4 as if such Mutual Fund Participants are Members. If any loss or liability remains thereafter and there are no continuing Mutual Fund Participants, NSCC would proceed with loss allocations to Members for a Defaulting Member Event in accordance with proposed Section 4 of Rule 4.

As proposed, Section 13 would reduce NSCC's retention period of Mutual Fund Deposits from ninety (90) days under the current Section 6 of Rule 4 to thirty (30) calendar days. Specifically, NSCC is proposing that a Mutual Fund Participant that elects to withdraw from membership would be entitled to the return of its Mutual Fund Deposit no later than thirty (30) calendar days after all of its transactions have settled and it has satisfied all of its matured and contingent obligations to NSCC for which such Mutual Fund Participant was responsible while a Mutual Fund Participant. NSCC is proposing this change in order to harmonize the retention period of Mutual Fund Deposit with the proposed Clearing Fund retention period in proposed Section 7 of Rule 4, as described above.

As proposed, Section 13 would make it clear that NSCC's rights, authority and obligations with respect to deposits to the Clearing Fund as set forth in Rule 4 would apply to Mutual Fund Deposits.

Section 14

NSCC is proposing to add a new Section 14 to Rule 4 that would be entitled "Insurance Deposits." Under the proposal, NSCC would consolidate provisions from various sections in current Rule 4 concerning Insurance Carrier/Retirement Services Members and group them into proposed Section 14. Aside from the consolidation, NSCC is not proposing any substantive changes to these provisions, except for changes to (i) reduce NSCC's retention period of Insurance Deposits when an Insurance Participant (as defined below and in the proposed rule change) elects to withdraw from membership, in order to harmonize it with proposed Section 7, as described above, and (ii) improve the transparency and accessibility of the provisions.

As in the current Rules, proposed Section 14 would provide that each Mutual Fund/Insurance Services Member that uses the Insurance and Retirement Processing Services and each Insurance Carrier/Retirement Services Member (collectively, "Insurance Participants") may be required to make a cash deposit to the Clearing Fund in the amounts determined in accordance with Procedure XV and other applicable Rules (its "Insurance Deposit" and, unless specified otherwise, for the purposes of the Rules, Required Fund Deposits shall include Insurance Deposits). Proposed Section 14 would also provide that if any Insurance Participant fails to satisfy any obligation to NSCC relating to the Insurance and Retirement Processing Services, NSCC would first apply such Insurance Participant's Insurance Deposit. If after such application any loss or liability remains, NSCC would allocate the remaining loss or liability to the other Insurance Participants in successive rounds of loss allocations in each case up to the aggregate of Insurance Deposits from non-defaulting Insurance Participants, and after the first such round, Insurance Participants that have not submitted a Loss Allocation Withdrawal Notice in accordance with proposed Section 6 of Rule 4, following the procedures and timeframes set forth in proposed Sections 4 and 6 of Rule 4 as if such Insurance Participants are Members. If any loss or liability remains thereafter and there are no continuing Insurance Participants, NSCC would proceed with loss allocations to Members for a Defaulting Member Event in accordance with proposed Section 4 of Rule 4.

As proposed, Section 14 would reduce NSCC's retention period of Insurance Deposits from ninety (90) days under the current Section 6 of Rule 4 to thirty (30) calendar days. Specifically, NSCC is proposing that an Insurance Participant that elects to withdraw from membership would be entitled to the return of its Insurance Deposit no later than thirty (30) calendar days after all of its transactions have settled and it has satisfied all of its matured and contingent obligations to NSCC for which such Insurance Participant was responsible while an Insurance Participant. NSCC is proposing this change in order to harmonize the retention period of Insurance Deposit with the proposed Clearing Fund retention period in proposed Section 7 of Rule 4, as described above.

As proposed, Section 14 would make it clear that NSCC's rights, authority and obligations with respect to deposits to the Clearing Fund as set forth in Rule 4 would apply to Insurance Deposits.

B. Proposed Changes to Addendum E (Statement of Policy—Application of Retained Earnings—Member Impairments) and Addendum K (Interpretation of the Board of Directors—Application of Clearing Fund)

Addendum E is a statement of policy that currently provides that NSCC will apply no less than twenty-five (25) percent of its retained earnings to cover losses or liabilities from a Member's impairment that is not otherwise satisfied by the impaired Member's Clearing Fund deposit. NSCC is proposing to delete Addendum E in its entirety because it would no longer be relevant given the proposed rule change relating to the Corporate Contribution discussed above.

NSCC is proposing to modify Addendum K to delete all provisions associated with loss allocation and application of the Clearing Fund in connection with a loss or liability incurred by NSCC, including modifying the title of Addendum K. These provisions would no longer be necessary under the proposed rule change because the loss allocation process in its entirety would be governed by Rule 4. In addition, the current language in Addendum K regarding allocation by System would no longer be applicable under the proposed rule change as described above. NSCC would retain the provisions in Addendum K that pertain to NSCC's guaranty and rename Addendum K "The Corporation's Guaranty." NSCC is also proposing to replace "Rules" with "Rules and Procedures" to better reflect the name of NSCC's rulebook.

(iii) Other Proposed Rule Changes

NSCC is proposing changes to Rule 1 (Definitions and Descriptions), Rule 2B (Ongoing Membership Requirements and Monitoring), Rule 4(A) (Supplemental Liquidity Deposits), Rule 13 (Exception Processing), Rule 15 (Assurances of Financial Responsibility and Operational Capability), Rule 42 (Wind-Down of a Member, Fund Member or Insurance Carrier/Retirement Services Member), Procedure III (Trade Recording Service (Interface with Qualified Clearing Agencies)), Procedure XV (Clearing Fund Formula and Other Matters), and Addendum O (Admission of Non-US Entities as Direct NSCC Members). NSCC is proposing changes to these Rules in order to conform them with the proposed changes to Rule 4 as well as to make certain technical changes to these Rules.

Specifically, NSCC is proposing to add the following defined terms to Rule 1, in alphabetical order: Actual Deposit, Average RFD, Clearing Fund Cash, Corporate Contribution, Declared Non-Default Loss Event, Defaulting Member, Defaulting Member Event, Eligible Letter of Credit, Event Period, Insurance Deposit, Insurance Participant, Issuer, Lender, Loss Allocation Cap, Loss Allocation Notice, Loss Allocation Withdrawal Notice, Loss Allocation Withdrawal Notification Period, Mutual Fund Deposit, Mutual Fund Participant, Required Fund Deposit, Termination Date, and Voluntary Termination Notice.

NSCC is proposing to delete the defined term "The Corporation" in Rule 1 and replace it with "Corporation" in Rule 1. NSCC is proposing to replace "Required Deposits" with "Required Fund Deposits" in Rule 2B, Rule 4(A), Rule 15, Rule 42, Procedure III, and Procedure XV. NSCC is proposing to replace "Rules" with "Rules and Procedures" in Rule 1, Rule 2B, Rule 13, Rule 15, and Procedure III. NSCC is also proposing to replace "Letter of Credit" with "Eligible Letter of Credit" in Rule 42 and Addendum O.

In addition, in Section 5 of Rule 2B, NSCC proposes to change the reference to Section 8 of Rule 4 to reflect the updated section number, which would be to Section 4 of Rule 4. NSCC is also proposing conforming changes to this section to ensure that termination provisions in the Rules, whether voluntary or in response to a loss allocation, are consistent with one another to the extent appropriate.

Currently, Section 5 of Rule 2B provides that participants may elect to voluntarily retire their membership by providing NSCC with written notice of such termination. Such termination will not be effective until accepted by NSCC, which shall be evidenced by a notice to NSCC's participants announcing the participant's retirement and the effective date of the retirement, which is defined as the "Retirement Date." This section also provides that a participant's voluntary termination of membership shall not affect its obligations to NSCC.

Where appropriate, NSCC is proposing changes to align Section 5 of Rule 2B with the proposed new Section 6 of Rule 4, both of which address termination of membership.

Specifically, NSCC is proposing to rename the subheading of Section 5 of Rule 2B to "Voluntary Termination" and to change "retirement" to "termination" and "Retirement Date" to "Termination Date" throughout Section 5 of Rule 2B. NSCC is also proposing to provide that when a participant elects to

voluntarily terminate its membership by providing NSCC a written notice of such termination ("Voluntary Termination Notice"), the participant must specify in its Voluntary Termination Notice a desired date for its withdrawal, provided such date shall not be prior to the scheduled final settlement date of any remaining obligation owed by the participant to NSCC as of the time such Voluntary Termination Notice is submitted to NSCC, unless otherwise approved by NSCC. NSCC is retaining the provision that makes it clear that the termination will not be effective until accepted by NSCC.58 NSCC is also retaining the provision that describes NSCC's acceptance of the termination; however, NSCC is proposing to make it clear that such acceptance, as evidenced by a notice to NSCC's participants, would (i) be no later than ten (10) business days after the receipt of the Voluntary Termination Notice from the participant and (ii) announce the last trade date for the participant instead of the Termination Date. In addition, NSCC is proposing to make it clear that the Termination Date would be the final settlement date of all transactions of the participant. NSCC is proposing these clarifying changes so that the Rules would align more closely with NSCC's current practice.

As an example, Member A submits a Voluntary Termination Notice to NSCC on April 1st indicating its desired termination date is June 15th. NSCC would accept such termination request by issuing a notice to Members within 10 business days from April 1st; such notice would provide that the last trade date for Member A is June 12th, and the effective date of Member A's NSCC membership termination would be the final settlement date of all transactions of Member A. In contrast, if Member A submits a Voluntary Termination Notice on April 1st and indicates its desired termination date is April 5th, NSCC would either (i) accept such termination notice by issuing a notice to Members on or before April 5th; such notice would provide that the last trade date for Member A is April 2nd, and the effective date of Member A's NSCC membership termination would be the final settlement date of all transactions of Member A, or (ii) if NSCC requires

additional time to process the termination, NSCC would accept such termination notice by issuing notice to Members after April 5th but still within 10 business days from April 1st; such notice would provide that the last trade date for Member A is a date after April 2nd, and the effective date of Member A's NSCC membership termination would be the final settlement date of all transactions of Member A.

NSCC is also proposing to clarify that after the close of business on the Termination Date,⁵⁹ a participant that terminates its membership shall no longer be eligible or required to submit transactions to NSCC for clearance and settlement, unless the Board of Directors determines otherwise in order to ensure an orderly liquidation of the participant's open obligations. If any transaction is submitted to NSCC by such participant that is scheduled to settle after the Termination Date, the participant's Voluntary Termination Notice would be deemed void and the participant would remain subject to the Rules as if it had not given such notice. Furthermore, NSCC is proposing to add a sentence to Section 5 of Rule 2B to refer participants to Sections 7, 13 and 14 of Rule 4, as applicable, regarding provisions on the return of a participant's Clearing Fund deposit and to specify that if an Event Period were to occur after a participant has submitted its Voluntary Termination Notice but on or prior to the Termination Date, in order for such participant to benefit from its Loss Allocation Cap pursuant to Section 4 of Rule 4, the participant would need to comply with the provisions of Section 6 of Rule 4 and submit a Loss Allocation Withdrawal Notice, which notice, upon submission, would supersede and void any pending Voluntary Termination Notice previously submitted by the participant. As an example, if an Event Period occurs after submission of the Voluntary Termination Notice by a Member but on or prior to the Termination Date, and the Member does not subsequently submit a Loss Allocation Withdrawal Notice as proposed in Section 6 of Rule 4, then the Member would not benefit from its Loss Allocation Cap, i.e., the Member would remain obligated for its pro rata share of losses and liabilities with respect to any Event Period that commenced on or prior to the Termination Date.

In Rule 4(A), NSCC proposes to amend Section 11 to update a cross-

⁵⁸ Unlike the Voluntary Termination Notice, the Loss Allocation Withdrawal Notice as proposed in Section 6 of Rule 4 does not require explicit acceptance by NSCC to be effective. NSCC believes that requiring explicit acceptance of the Loss Allocation Withdrawal Notice could complicate the loss allocation process and potentially result in membership withdrawal being delayed as well as detract from the objective to have NSCC know on a timely basis which Members would remain subject to the subsequent rounds of loss allocation.

⁵⁹ Account(s) of a terminating participant are generally deactivated after the close of business on the Termination Date.

reference to the time period for the refund of deposits to the Clearing Fund when a Member ceases to be a participant in order to align it with proposed Section 7 of Rule 4, which would reduce the time period from 90 days to 30 calendar days. NSCC is also proposing to add a reference to Section 13 of Rule 4 in clause (c) of Section 13 of Rule 4(A) in order to specify that a Special Activity Supplemental Deposit of a Member may be used to satisfy a loss or liability as provided in such new proposed Section 13. NSCC is also proposing technical changes in Sections 2 and 13 of Rule 4(A) to reflect new proposed defined terms in the Rules.

In Rule 13, NSCC would replace "System" with "system" to reflect the proposed deletion of "System" as a defined term from Rule 4 and Addendum K. In Procedure XV, NSCC would replace "Qualified Securities Depository" with "DTC" to be consistent with the proposed change in Section 1 of Rule 4.

Member Outreach

Beginning in August 2017, NSCC conducted outreach to Members in order to provide them with advance notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

Implementation Timeframe

Pending Commission approval, NSCC expects to implement this proposal within two (2) business days after approval. Members would be advised of the implementation date of this proposal through issuance of an NSCC Important Notice.

2. Statutory Basis

NSCC believes that the proposed rule change is consistent with the requirements of the Act, and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, NSCC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act ⁶⁰ and Rules 17Ad–22(e)(13) and 17Ad–22(e)(23)(i),⁶¹ each as promulgated under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the

safeguarding of securities and funds which are in the custody or control of NSCC or for which it is responsible. 62 The proposed rule changes to (1) modify the calculation and application of NSCC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Member withdrawal process in connection with the loss allocation process, and (4) implement a "lookback" period to calculate a Member's loss allocation obligation (which would replace the current calculation of a Member's loss allocation obligation based on the Member's activity in each of the various services or "Systems" offered by NSCC) and its Loss Allocation Cap, taken together, are intended to enhance the overall resiliency of NSCC's loss allocation process.

By modifying the calculation of NSCC's corporate contribution, NSCC would apply a mandatory fixed percentage of its General Business Risk Capital Requirement (as compared to the current Rules which provide for "no less than" a percentage of retained earnings), which would provide greater transparency and accessibility to Members as to how much NSCC would contribute in the event of a loss or liability. By modifying the application of NSCC's corporate contribution to apply to Declared Non-Default Loss Events, in addition to Defaulting Member Events, on a mandatory basis, NSCC would expand the application of its corporate contribution beyond losses and liabilities from Member impairments, which would better align the interests of NSCC with those of its Members by stipulating a mandatory application of the Corporate Contribution to a Declared Non-Default Loss Event prior to any allocation of the loss among Members. Taken together, these proposed rule changes would enhance the overall resiliency of NSCC's loss allocation process by enhancing the calculation and application of NSCC's Corporate Contribution, which is one of the key elements of NSCC's loss allocation process. Moreover, by providing greater transparency and accessibility to Members, as stated above, the proposed rule changes regarding the Corporate Contribution, including the proposed replenishment period, would allow Members to better assess the adequacy of NSCC's loss allocation process.

By introducing the concept of an Event Period, NSCC would be able to group Defaulting Member Events and Declared Non-Default Loss Events occurring in a period of ten (10) business days for purposes of allocating losses to Members. NSCC believes that the Event Period would provide a defined structure for the loss allocation process to encompass potential sequential Defaulting Member Events or Declared Non-Default Loss Events that are likely to be closely linked to an initial event and/or market dislocation episode. Having this structure would enhance the overall resiliency of NSCC's loss allocation process because NSCC would be better equipped to address losses that may arise from multiple Defaulting Member Events and/or Declared Non-Default Loss Events that arise in quick succession. Moreover, the proposed Event Period structure would provide certainty for Members concerning their maximum exposure to mutualized losses with respect to such events.

By introducing the concept of "rounds" (and accompanying Loss Allocation Notices) and applying this concept to the timing of loss allocation payments and the Member withdrawal process in connection with the loss allocation process, NSCC would (i) set forth a defined amount that it would allocate to Members during each round (i.e., the round cap), (ii) advise Members of loss allocation obligation information as well as round information through the issuance of Loss Allocation Notices, and (iii) provide Members with the option to limit their loss allocation exposure after the issuance of the first Loss Allocation Notice in each round. These proposed rule changes would enhance the overall resiliency of NSCC's loss allocation process because they would enable NSCC to continue the loss allocation process in successive rounds until all of NSCC's losses are allocated and enable NSCC to identify continuing Members for purposes of calculating subsequent loss allocation obligations in successive rounds. Moreover, the proposed rule changes would define for Members a clear manner and process in which they could cap their loss allocation exposure to NSCC.

By implementing a "look-back" period to calculate a Member's loss allocation obligations and its Loss Allocation Cap, NSCC would discourage Members from reducing their settlement activity during a time of stress primarily to limit their loss allocation obligations. By determining a Member's loss allocation obligations based on the average of its Required Fund Deposit over a look-back period and its Loss

^{60 15} U.S.C. 78q-1(b)(3)(F).

^{61 17} CFR 240.17Ad–22(e)(13) and (e)(23)(i).

⁶² 15 U.S.C. 78q-1(b)(3)(F).

Allocation Cap based on the greater of its Required Fund Deposit or the average thereof over a look-back period, NSCC would be able to calculate a Member's pro rata share of losses and liabilities based on the amount of risk that the Member brings to NSCC. These proposed rule changes would enhance the overall resiliency of NSCC's loss allocation process because they would deter Members from reducing their settlement activity during a time of stress primarily to limit their Loss Allocation Caps.

Taken together, the foregoing proposed rule changes would establish a stronger (for all the reasons discussed above) and clearer loss allocation process for NSCC, which NSCC believes would allow it to take timely action to address losses. The ability to timely address losses would allow NSCC to continue to meet its clearance and settlement obligations, especially in circumstances that may involve a series of substantially contemporaneous loss events. Therefore, NSCC believes that these proposed rule changes would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

By reducing the time within which NSCC is required to return a former Member's Clearing Fund deposit, NSCC would enable firms that have exited NSCC to have access to their funds sooner than under the current Rules while at the same time protecting NSCC and its provision of clearance and settlement services because such return would only occur if all obligations of the terminating Member to NSCC have been satisfied. As such, NSCC would maintain the requisite level of Clearing Fund deposit to ensure that it can continue to meet its clearance and settlement obligations. Therefore, NSCC believes that this proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

The proposed rule changes to NSCC's voluntary termination provisions would improve the clarity of the Rules and help to ensure that NSCC's voluntary termination process is transparent and clear to Members. Having clear voluntary termination provisions would enable Members to better understand NSCC's voluntary termination process and provide Members with increased predictability and certainty regarding their rights and obligations with respect to such process. Enabling Members to readily understand NSCC's voluntary termination process and their rights and obligations in connection therewith

would help the withdrawing Member and the membership at large to know when a Member is no longer a Member of NSCC for clearance and settlement and would thereby promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

Rule 17Ad-22(e)(13) under the Act requires, in part, that NSCC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure NSCC has the authority and operational capacity to take timely action to contain losses and continue to meet its obligations. 63 As described above, the proposed rule changes to (1) modify the calculation and application of NSCC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Member withdrawal process in connection with the loss allocation process, and (4) implement a "look-back" period to calculate a Member's loss allocation obligation (which would replace the current calculation of a Member's loss allocation obligation based on the Member's activity in each of the various services or "Systems" offered by NSCC) and its Loss Allocation Cap, taken together, are designed to enhance the resiliency of NSCC's loss allocation process. Having a resilient loss allocation process would help ensure that NSCC can effectively and timely address losses relating to or arising out of either the default of one or more Members or one or more non-default loss events, which in turn would help NSCC contain losses and continue to meet its clearance and settlement obligations. Therefore, NSCC believes that the proposed rule changes to enhance the resiliency of NSCC's loss allocation process are consistent with Rule 17Ad-22(e)(13) under the Act.

Rule 17Ad–22(e)(23)(i) under the Act requires NSCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to publicly disclose all relevant rules and material procedures, including key aspects of NSCC's default rules and procedures. ⁶⁴ The proposed rule changes to (i) align the loss allocation rules of the DTCC Clearing Agencies, (ii) improve the overall transparency and accessibility of the provisions in the Rules governing loss allocation, and (iii) make conforming and technical changes, would not only ensure that

NSCC's loss allocation rules are, to the extent practicable and appropriate, consistent with the loss allocation rules of other DTCC Clearing Agencies, but also would help to ensure that NSCC's loss allocation rules are transparent and clear to Members. Aligning the loss allocation rules of the DTCC Clearing Agencies would provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and clear loss allocation rules would enable Members to better understand the key aspects of NSCC's default rules and procedures and provide Members with increased predictability and certainty regarding their exposures and obligations. As such, NSCC believes that the proposed rule changes to align the loss allocation rules of the DTCC Clearing Agencies as well as to improve the overall transparency and accessibility of NSCC's loss allocation rules are consistent with Rule 17Ad-22(e)(23)(i) under the Act.

Similarly, the proposed rule changes to NSCC's voluntary termination provisions would improve the clarity of the Rules and help to ensure that NSCC's voluntary termination process is transparent and clear to Members. Having clear voluntary termination provisions would enable Members to better understand NSCC's voluntary termination process and provide Members with increased predictability and certainty regarding their rights and obligations with respect to such process. As such, NSCC believes that the proposed rule changes to the voluntary termination provision are also consistent with Rule 17Ad-22(e)(23)(i) under the Act.

(B) Clearing Agency's Statement on Burden on Competition

NSCC does not believe that the proposed rule changes to enhance the resiliency of NSCC's loss allocation process would impact competition. 65 As described above, the proposed rule changes to (1) modify the calculation and application of NSCC's corporate contribution, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Member withdrawal process in connection with the loss allocation process, and (4) implement a "look-back" period to calculate a Member's loss allocation obligation (which would replace the current calculation of a Member's loss

^{63 17} CFR 240.17Ad-22(e)(13).

^{64 17} CFR 240.17Ad-22(e)(23)(i).

^{65 15} U.S.C. 78q-1(b)(3)(I).

allocation obligation based on the Member's activity in each of the various services or "Systems" offered by NSCC) and its Loss Allocation Cap, taken together, are intended to enhance the overall resiliency of NSCC's loss allocation process, and would apply equally to all Members. While the proposed rule changes would amend the manner in which NSCC's corporate contribution and loss allocation are calculated and applied, such proposed rule changes would maintain NSCC's current core loss allocation waterfall in the case of a loss relating to or arising out of the default of a Member for whom NSCC has ceased to act following application of the defaulting Member's resources, i.e., NSCC's corporate contribution and loss allocation among Members. With respect to a loss or liability arising from a non-default loss event, the proposed rule changes clarify NSCC's contribution to such loss and liability, but, as with losses and liabilities arising from a Member default event, the proposed rule changes would maintain the loss mutualization requirement under the current Rule 4. While the calculation of the loss obligations associated with non-default losses would change under the proposal, NSCC would maintain this aspect of the loss allocation waterfall (i.e., loss mutualization among Members for non-default losses). Based on the foregoing, NSCC believes that these proposed rule changes to enhance the resiliency of NSCC's loss allocation process would not have any impact on competition.

NSCC does not believe the proposed rule change to reduce the time within which NSCC is required to return a former Member's Clearing Fund deposit would impact competition.⁶⁶ This proposed rule change is intended to enable firms who have exited NSCC to have use of their Clearing Fund deposit sooner, while at the same time protecting NSCC because such return would only occur if all obligations of the terminated Member to NSCC have been satisfied. While the proposed rule change would reduce the applicable timeframe, it does not change the requirement that the return occur after all obligations to NSCC have been satisfied and the proposed rule change would apply equally to all Members. Based on the foregoing, NSCC believes that the proposed rule change to reduce the time within which NSCC is required to return a former Member's Clearing Fund deposit would not have any impact on competition.

NSCC also does not believe that the proposed rule changes to (i) align the loss allocation rules of the DTCC Clearing Agencies, (ii) increase the transparency and accessibility of provisions in the Rules governing loss allocation, (iii) clarify NSCC's voluntary termination provisions, and (iv) make conforming and technical changes, would impact competition.⁶⁷ These changes would apply equally to all Members. Alignment of the loss allocation rules of the DTCC Clearing Agencies are intended to increase the consistency of the Rules with the rules of other DTCC Clearing Agencies in order to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and accessible provisions in the Rules governing loss allocation are intended to improve the readability and clarity of the Rules regarding the loss allocation process. Clarifying NSCC's voluntary termination provisions would improve the clarity of the Rules and help to ensure that NSCC's voluntary termination process is transparent and clear to Members. Making conforming and technical changes to ensure the Rules remain clear and accurate would facilitate Members' understanding of the Rules and their obligations thereunder. As such, NSCC believes that these proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to this proposed rule change have not been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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-NSCC-2017-018 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-NSCC-2017-018. 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 website (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 website 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 NSCC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NSCC-2017-018 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 68

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15368 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83629; File No. SR–DTC–2017–022]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Amend the Loss Allocation Rules and Make Other Changes

July 13, 2018.

On December 18, 2017, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–DTC–2017–022 ("Proposed Rule Change") to amend the loss allocation rules and make other changes; the Proposed Rule Change was published for comment in the **Federal Register** on January 8, 2018. On February 8, 2018,

the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.² On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change; on June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the Proposed Rule Change.³ On June 28, 2018, DTC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.4 As of the date of this release, the Commission has not received any comments on the Proposed Rule Change.

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by DTC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change would revise Rule 4 (Participants Fund and Participants Investment) to (i) provide separate sections for (x) the use of the Participants Fund ⁵ as a liquidity resource for settlement and (y) loss allocation among Participants of losses and liabilities arising out of Participant defaults or due to non-default events; and (ii) enhance the resiliency of DTC's loss allocation process so that DTC can

take timely action to contain multiple loss events that occur in succession during a short period of time. In connection therewith, the proposed rule change would (i) align the loss allocation rules of the three clearing agencies of The Depository Trust & Clearing Corporation ("DTCC"), namely DTC, National Securities Clearing Corporation ("NSCC"), and Fixed Income Clearing Corporation ("FICC") (collectively, the "DTCC Clearing Agencies"), so as to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies, (ii) increase transparency and accessibility of the provisions relating to the use of the Participants Fund as a liquidity resource for settlement and the loss allocation provisions, by enhancing their readability and clarity, (iii) require a defined corporate contribution to losses and liabilities that are incurred by DTC prior to any allocation among Participants, whether such losses and liabilities arise out of Participant defaults or due to non-default events, (iv) reduce the time within which DTC is required to return a former Participant's Actual Participants Fund Deposit, and (v) make conforming and technical changes. In addition, the proposed rule change would amend Section 6 of Rule 4 to clarify the requirements for a Participant that wants to voluntarily terminate its business with DTC, and to align, where appropriate, with the proposed voluntary termination provisions of the NSCC and FICC rules. The proposed rule change would also amend Rule 1 (Definitions; Governing Law) to add cross-references to terms that would be defined in proposed Rule 4, and would amend Rule 2 (Participants and Pledgees), in relevant part, to align with proposed Section 6 of Rule 4, as discussed below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

¹¹⁵ U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively. Securities Exchange Act Release No. 82426 (January 2, 2018), 83 FR 913 (January 8, 2018) (SR-DTC-2017-022). On December 18, 2017, DTC filed the Proposed Rule Change as advance notice SR-DTC-2017-804 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release No. 82582 (January 24, 2018), 83 FR 4297 (January 30, 2018) (SR-DTC-2017-804). On April 10, 2018, the Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Commission's Request for Additional Information," available at http:// www.sec.gov/rules/sro/dtc-an.shtml. On June 28, 2018, DTC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, DTC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/dtc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 Û.S.C. 5465(e)(1)(E) and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at http://www.sec.gov/

rules/sro/dtc-an.shtml. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

Securities Exchange Act Release No. 82670
 (February 8, 2018), 83 FR 6626 (February 14, 2018)
 (SR-DTC-2017-022; SR-FICC-2017-022; SR-NSCC-2017-018).

³ Securities Exchange Act Release No. 82914 (March 20, 2018), 83 FR 12978 (March 26, 2018) (SR–DTC–2017–022); Securities Exchange Act Release No. 83510 (June 25, 2018), 83 FR 30791 (June 29, 2018) (SR–DTC–2017–022; SR–FICC–2017–022; SR–NSCC–2017–018).

⁴To promote the public availability and transparency of its post-notice amendment, DTC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the Commission's website at https://www.sec.gov/rules/sro/dtc.htm and thus been publicly available since June 29, 2018.

⁵Each capitalized term not otherwise defined herein has its respective meaning as set forth in the Rules, By-Laws and Organization Certificate of DTC ('Rules''), available at http://www.dtcc.com/legal/rules-and-procedures.aspx.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of the Amendment

This filing constitutes Amendment No. 1 ("Amendment") to rule filing SR-DTC-2017-022 ("Rule Filing") previously filed by DTC on December 18, 2017.6 This Amendment amends and replaces the Rule Filing in its entirety. DTC submits this Amendment in order to further clarify the operation of the proposed rule changes on loss allocation by providing additional information and examples. This Amendment would also clarify the requirements for a Participant that wants to voluntarily terminate its business with DTC. In particular, this Amendment would:

(i) Clarify that the term "Participant Default," referring to the failure of a Participant to satisfy any obligation to DTC, includes the failure of a Defaulting Participant to satisfy its obligations as

provided in Rule 9(B).7

(ii) Add the defined term "CTA Participant," which would be defined as a Participant for which the Corporation has ceased to act pursuant to Rule 10 (Discretionary Termination), Rule 11 (Voluntary Termination) or Rule 12

(Insolvency).

(iii) Clarify which Participants would be subject to loss allocation with respect to Default Loss Events (defined below) and Declared Non-Default Loss Events (defined below) occurring during an Event Period (defined below). Specifically, pursuant to the Amendment, proposed Section 5 of Rule 4 would provide that each Participant that is a Participant on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Default Loss Event (other than a Default Loss Event with respect to which it is the CTA Participant) and each Declared Non-Default Loss Event occurring during the Event Period. In addition, proposed Section 5 of Rule 4 would make it clear that any CTA Participant for which DTC ceases to act on a non-Business Day, triggering an

Event Period that commences on the next Business Day, would be deemed to be a Participant on the first day of that Event Period.

(iv) Clarify the obligations and Loss Allocation Cap (defined below) of a Participant that terminates its business with DTC in respect of a loss allocation round. Specifically, pursuant to the Amendment, the Participant would nevertheless remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated under Rule 4; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap, as fixed in the loss allocation round for which it withdrew.

(v) Clarify that each CTA Participant would be obligated to DTC for the entire amount of any loss or liability incurred by DTC arising out of or relating to any Default Loss Event with respect to such CTA Participant. To the extent that such loss or liability is not satisfied pursuant to proposed Section 3 of Rule 4, DTC would apply a Corporate Contribution and charge the remaining amount of such loss or liability as provided in proposed Section 5 of Rule 4.

(vi) Clarify that, although a CTA Participant would not be allocated a ratable share of losses and liabilities arising out of or relating to its own Default Loss Event, it would remain obligated to DTC for such losses and liabilities. More particularly, pursuant to the Amendment, the proposed rule change would provide that no loss allocation under proposed Rule 4 would constitute a waiver of any claim DTC may have against a Participant for any losses or liabilities to which the Participant is subject under DTC Rules and Procedures, including, without limitation, any loss or liability to which it may be subject under proposed Rule

(vii) For enhanced transparency and to align, where appropriate, with the rules of NSCC and FICC, clarify the process for the Voluntary Retirement (defined below) of a Participant.

In addition, pursuant to the Amendment, DTC is making other clarifying and technical changes to the proposed rule change, as proposed berein

Nature of the Proposed Change

The proposed rule change would revise Rule 4 (Participants Fund and Participants Investment) to (i) provide separate sections for (x) the use of the Participants Fund as a liquidity resource for settlement and (y) loss allocation among Participants of losses and liabilities arising out of Participant defaults or due to non-default events;

and (ii) enhance the resiliency of DTC's loss allocation process so that DTC can take timely action to contain multiple loss events that occur in succession during a short period of time. In connection therewith, the proposed rule change would (i) align the loss allocation rules of the DTCC Clearing Agencies, so as to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies,8 (ii) increase transparency and accessibility of the provisions relating to the use of the Participants Fund as a liquidity resource for settlement and the loss allocation provisions, by enhancing their readability and clarity, (iii) require a defined corporate contribution to losses and liabilities that are incurred by DTC prior to any allocation among Participants, whether such losses and liabilities arise out of Participant defaults or due to non-default events, (iv) reduce the time within which DTC is required to return a former Participant's Actual Participants Fund Deposit, and (v) make conforming and technical changes. In addition, the proposed rule change would amend Section 6 of Rule 4 to clarify the requirements for a Participant that wants to voluntarily terminate its business with DTC, and to align, where appropriate, with the proposed voluntary termination provisions of the NSCC and FICC rules. The proposed rule change would also amend Rule 1 (Definitions; Governing Law) to add cross-references to terms that would be defined in proposed Rule 4, and would amend Rule 2 (Participants and Pledgees), in relevant part, to align with proposed Section 6 of Rule 4, as discussed below.

(i) Background

Current Rule 4 provides a single set of tools and a common process for the use of the Participants Fund for both liquidity purposes to complete settlement among non-defaulting Participants, if one or more Participants

⁶ See Securities Exchange Act Release No. 82426 (January 2, 2018), 83 FR 913 (January 8, 2018) (SR– DTC–2017–022).

⁷ Although Rule 4 is being amended to align with NSCC and FICC, where appropriate, a "Defaulting Participant" is not analogous to a "Defaulting Member" under the proposed NSCC and FICC rules. This is because the term "Defaulting Participant" already has a specific meaning pursuant to Rule 9(B) which is necessary and appropriate to that Rule. Instead, the proposed new term "CTA Participant" would be analogous to the NSCC and FICC proposed term "Defaulting Member."

 $^{^8\,\}mbox{On}$ December 18, 2017, NSCC and FICC submitted proposed rule changes and advance notices to enhance their rules regarding allocation of losses. Securities Exchange Act Release Nos. 82428 (January 2, 2018), 83 FR 897 (January 8, 2018) (SR-NSCC-2017-018), and 82584 (January 24, 2018), 83 FR 4377 (January 30, 2018) (SR-NSCC-2017-806); Securities Exchange Act Release Nos. 82427 (January 2, 2018), 83 FR 854 (January 8, 2018) (SR-FICC-2017-022) and 82583 (January 24, 2018), 83 FR 4358 (January 30, 2018) (SR-FICC-2017-806). On June 28, 2018, NSCC and FICC filed proposed amendments to the proposed rule changes and advance notices with the Commission and the Board of Governors of the Federal Reserve System, respectively, available at http://www.dtcc.com/ legal/sec-rule-filings.aspx.

fails to settle,⁹ and for the satisfaction of losses and liabilities due to Participant defaults ¹⁰ or certain other losses or

⁹DTC is a central securities depository providing key services that are structured to support daily settlement of book-entry transfers of securities, in accordance with its Rules and Procedures. In particular, Rule 9(A) (Transactions in Securities and Money Payments), Rule 9(B) (Transactions in Eligible Securities), Rule 9(C) (Transactions in MMI Securities), Rule 9(D) (Settling Banks), and Rule 9(E) (Clearing Agency Agreements) provide the mechanism to achieve a "DVP Model 2 Deferred Net Settlement System" (as defined in Annex D of the Principles for Financial Market Infrastructures issued by The Committee on Payments and Market Infrastructures and the Technical Committee of the International Organization of Securities Commissions (April 2012), available at https:// www.bis.org/cpmi/publ/d101a.pdf. Briefly, in relevant part, Rule 9(B) provides that "[e]ach Participant and the Corporation shall settle the balance of the Settlement Account of the Participant on a daily basis in accordance with these Rules and the Procedures. Except as provided in the Procedures, the Corporation shall not be obligated to make any settlement payments to any Participants until the Corporation has received all of the settlement payments that Settling Banks and Participants are required to make to the Corporation." Supra note 5. Pursuant to these provisions of Rule 9(B), securities will be delivered to Participants that satisfy their settlement obligations in the end-of-day net settlement process.

10 The failure of a Participant to satisfy its settlement obligation constitutes a liability to DTC. Insofar as DTC undertakes to complete settlement among Participants other than the Participant that failed to settle, that liability may give rise to losses as well. DTC is designed to provide settlement finality at the end of the day and notwithstanding the failure to settle of a Participant or Affiliated Family of Participants with the largest net settlement obligation, a "cover 1" standard. There are no reversals of deliveries; a Participant that fails to settle will not receive securities that were intended to be delivered to it, because it has not paid for them. These securities, among others, serve as collateral for DTC to use to secure a borrowing of funds in order, in accordance with its Rules and Procedures, to settle with non-defaulting Participants (including those delivering Participants that delivered to the non-settling Participant). To this end, delivery versus payment transactions ("DVP") will not be processed intraday to a receiving Participant that will incur a related payment obligation unless that Participant satisfies risk management controls. The two risk management controls are the Collateral Monitor and Net Debit Cap. Net Debit Caps limit the potential settlement obligation of any Participant to an amount for which DTC has sufficient liquidity resources to cover this risk. The Collateral Monitor tests whether a Participant has sufficient collateral for DTC to pledge or liquidate if that Participant were to fail to meet its settlement obligation. To process a DVP, the value of the delivery that is debited to the receiving Participant cannot cause the net debit balance of the Participant to exceed its Net Debit Cap, and the amount of the net debit balance after giving effect to the debit must be fully collateralized. Accordingly, DTC may incur a liability or loss whenever it completes settlement despite the failure to settle of a Participant, or Affiliated Family of Participants, because it is either using the Participants Fund deposits of other Participants in the manner specified in existing and proposed Rule 4 and/or borrowing the necessary funds. DTC obligations under the line of credit include the obligation to pay interest on loans outstanding and to repay the loan; the Participants Fund is designed as not only a direct liquidity resource but as a back-up liquidity resource to

liabilities incident to the business of DTC.¹¹ The proposed rule change would amend and add provisions to separate use of the Participants Fund as a liquidity resource to complete settlement, reflected in proposed Section 4 of Rule 4, and for loss allocation, reflected in proposed Section 5 of Rule 4. There wouldn't be any substantive change to the rights and obligations of Participants under proposed Sections 4 and 5 of Rule 4.12 The proposed rule changes reinforce the distinction, conceptual and sequential, between the mechanisms to complete settlement on a Business Day and to mutualize losses that may result from a failure to settle, or other loss-generating events. The change is also proposed so that the loss allocation provisions of proposed Section 5 of Rule 4 more closely align to similar provisions of the NSCC and FICC rules, to the extent appropriate.

The proposed rule change would retain the core principles of current Rule 4 for both application of the Participants Fund as a liquidity resource to complete settlement and for loss allocation, while clarifying or refining certain provisions and introducing certain new concepts relating to loss allocation. In connection with the use of the Participants Fund as a liquidity resource to complete settlement when a Participant fails to settle, the proposed rule would introduce the term "pro rata settlement charge," for the use of the Participants Fund to complete settlement as apportioned among nondefaulting Participants. The existing term generically applied to such a use or to a loss allocation is simply a "pro rata charge".13

For loss allocation, the proposed rule change, like current Rule 4, would continue to apply to both default and non-default losses and liabilities, and, to the extent allocated among Participants, would be charged ratably in accordance

satisfy these liabilities. As to the Participants Fund itself, DTC undertakes in Section 9 of existing and proposed Rule 4, to restore funds to Participants whose deposits may have been charged if there is ultimately any excess recovery. It should be noted that the Defaulting Participant remains principally obligated for all losses, costs and expenses associated with its Participant Default and, so, a recovery out of the estate of a Defaulting Participant is at least a hypothetical possibility.

with their Required Participants Fund Deposits. 14 A new provision would require DTC to contribute to a loss or liability, either arising from a Participant default or non-default event, prior to any allocation among Participants. The proposed rule change would also introduce the new concepts of an "Event Period" and a "round" to address the allocation of losses arising from multiple events that occur in succession during a short period of time. These proposed rule changes would be substantially similar in these respects to analogous proposed rule changes for NSCC and FICC.

Current Rule 4 Provides for Application of the Participants Fund Through Pro Rata Charges

Current Rule 4 addresses the Participants Fund and Participants Investment requirements and, among other things, the permitted uses of the Participants Fund and Participants Investment. ¹⁵ Pursuant to current Rule 4, DTC maintains a cash Participants Fund. The Required Participants Fund Deposit for any Participant is based on the liquidity risk it poses to DTC relative to other Participants.

Default of a Participant. Under current Section 3 of Rule 4, if a Participant is obligated to DTC and fails to satisfy any obligation, DTC may, in such order and in such amounts as DTC shall determine in its sole discretion: (a) Apply some or all of the Actual Participants Fund Deposit of such Participant to such obligation; (b) Pledge some or all of the shares of Preferred Stock of such Participant to its lenders as collateral security for a loan under the End-of-Day Credit Facility; 16 and/or (c) sell some or all of the shares of Preferred Stock of such Participant to other Participants (who shall be

¹¹ Section 1(f) of Rule 4 defines the term "business" with respect to DTC as "the doing of all things in connection with or relating to the Corporation's performance of the services specified in the first and second paragraphs of Rule 6 or the cessation of such services." Supra note 5.

¹² It may be noted that absent extreme circumstances, DTC believes that it is unlikely that DTC would need to act under proposed Sections 4 or 5 of Rule 4.

¹³ See Rule 4, Section 5, supra note 5.

¹⁴ It may be noted that for NSCC and FICC, the proposed rule changes for loss allocation include a "look-back" period to calculate a member's pro rata share and cap. The concept of a look-back or average is already built into DTC's calculation of Participants Fund requirements, which are based on a rolling sixty (60) day average of a Participant's six highest intraday net debit peaks.

¹⁵ Each Participant is required to invest in DTC Series A Preferred Stock, ratably on a basis calculated in substantially the same manner as the Required Participants Fund Deposit. The Preferred Stock constitutes capital of DTC and is also available for use as provided in current and proposed Section 3 of Rule 4. This proposed rule change does not alter the Required Preferred Stock Investment.

¹⁶ As part of its liquidity risk management regime, DTC maintains a 364-day committed revolving line of credit with a syndicate of commercial lenders, renewed every year. The committed aggregate amount of the End-of-Day Credit Facility (currently \$1.9 billion) together with the Participants Fund constitute DTC's liquidity resources for settlement. Based on these amounts, DTC sets Net Debit Caps that limit settlement obligations.

required to purchase such shares pro rata their Required Preferred Stock Investments at the time of such purchase), and apply the proceeds of such sale to satisfy such obligation.

Application of the Participants Fund. Current Section 4 of Rule 4 addresses the application of the Participants Fund if DTC incurs a loss or liability, which would include application of the Participants Fund to complete settlement 17 or the allocation of losses once determined, including non-default losses. For both liquidity and loss scenarios, current Section 4 of Rule 4 provides that an application of the Participants Fund would be apportioned among Participants ratably in accordance with their Required Participants Fund Deposits, less any additional amount that a Participant was required to Deposit to the Participants Fund pursuant to Section 2 of Rule 9(A).18 It also provides for the optional use of an amount of DTC's retained earnings and undivided profits.

After the Participants Fund is applied pursuant to current Section 4, DTC must promptly notify each Participant and the Commission of the amount applied and the reasons therefor.

Current Rule 4 further requires
Participants whose Actual Participants
Fund Deposits have been ratably
charged to restore their Required
Participants Fund Deposits, if such
charges create a deficiency. Such
payments are due upon demand.
Iterative pro rata charges relating to the
same loss or liability are permitted in
order to satisfy the loss or liability.

Rule 4 currently provides that a Participant may, within ten (10) Business Days after receipt of notice of any pro rata charge, notify DTC of its election to terminate its business with DTC, and the exposure of the terminating Participant for pro rata charges would be capped at the greater of (a) the amount of its Aggregate Required Deposit and Investment, as fixed immediately prior to the time of the first pro rata charge, plus 100% of the amount thereof, or (b) the amount of all prior pro rata charges attributable to the same loss or liability with respect to which the Participant has not timely exercised its right to terminate.

Overview of the Proposed Rule Changes

A. Application of Participants Fund to Participant Default and for Settlement

Proposed Section 3 of Rule 4 would retain the concept that when a Participant is obligated to DTC and fails to satisfy such obligation, which would be defined as a "Participant Default," DTC may apply the Actual Participants Fund Deposit of the Participant to such obligation to satisfy the Participant Default. The proposed rule change would reflect that the defined term "Participant Default," referring to the failure of a Participant to satisfy any obligation to DTC, includes the failure of a Defaulting Participant to satisfy its obligations as provided in Rule 9(B) (where "Defaulting Participant" is defined). The proposed definition of "Participant Default" is for drafting clarity and use in related provisions of proposed Rule 4.

Proposed Section 4 would address the situation of a Defaulting Participant failure to settle (which is one type of Participant Default) if the application of the Actual Participants Fund Deposit of that Defaulting Participant, pursuant to proposed Section 3, is not sufficient to complete settlement among Participants other than the Defaulting Participant (each, a "non-defaulting Participant").¹⁹

Proposed Section 4 would expressly state that the Participants Fund shall constitute a liquidity resource which may be applied by DTC, in such amounts as it may determine, in its sole

discretion, to fund settlement among non-defaulting Participants in the event of the failure of a Defaulting Participant to satisfy its settlement obligation on any Business Day. Such an application of the Participants Fund would be charged ratably to the Actual Participants Fund Deposits of the nondefaulting Participants on that Business Day. The pro rata charge per nondefaulting Participant would be based on the ratio of its Required Participants Fund Deposit to the sum of the Required Participants Fund Deposits of all such Participants on that Business Day (excluding any Additional Participants Fund Deposits in both the numerator and denominator of such ratio). The proposed rule change would identify this as a "pro rata settlement charge," in order to distinguish application of the Participants Fund to fund settlement from pro rata loss allocation charges that would be established in proposed Section 5 of Rule 4.

The calculation of each nondefaulting Participant's pro rata settlement charge would be similar to the current Section 4 calculation of a pro rata charge except that, for greater simplicity, it would not include the current distinction for common members of another clearing agency pursuant to a Clearing Agency Agreement.²⁰ For enhanced clarity as to the date of determination of the ratio, it would be based on the Required Participants Fund Deposits as fixed on the Business Day of the application of the Participants Fund, as opposed to the current language "at the time the loss or liability was discovered." 21

The proposed rule change would retain the concept that requires DTC, following the application of the Participants Fund to complete settlement, to notify each Participant and the Commission of the charge and the reasons therefor ("Settlement Charge Notice").

The proposed rule change also would retain the concept of providing each non-defaulting Participant an opportunity to elect to terminate its business with DTC and thereby cap its exposure to further pro rata settlement charges. The proposed rule change would shorten the notification period

¹⁷ In contrast to NSCC and FICC, DTC is not a central counterparty and does not guarantee obligations of its membership. The Participants Fund is a mutualized pre-funded liquidity and loss resource. As such, in contrast to NSCC and FICC, DTC does not have an obligation to "repay" the Participants Fund, and the application of the Participants Fund does not convert to a loss. See supra note 10.

¹⁸ Section 2 of Rule 9(A) provides, in part, "At the request of the Corporation, a Participant or Pledgee shall immediately furnish the Corporation with such assurances as the Corporation shall require of the financial ability of the Participant or Pledgee to fulfill its commitments and shall conform to any conditions which the Corporation, other Participants or Pledgees, including deposits to the Participants Fund . . ." Supra note 5. Pursuant to the proposed rule change, the additional amount that a Participant is required to Deposit to the Participants Fund pursuant to Section 2 of Rule 9(A) would be defined as an "Additional Participants Fund Deposit." This is not a new concept, only the addition of a defined term for greater clarity.

 $^{^{19}\,\}mathrm{As}$ described above, proposed Rule 4 splits the liquidity and loss provisions to more closely align to similar loss allocation provisions in NSCC and FICC rules. Pursuant to the proposed rule change, DTC would also align, where appropriate, the liquidity and loss provisions within proposed Rule 4. DTC would retain the existing Rule 4 concepts of calculating the ratable share of a Participant, charging each non-defaulting Participant a pro rata share of an application of the Participants Fund to complete settlement, providing notice to Participants of such charge, and providing each Participant the option to cap its liability for such charges by electing to terminate its business with DTC. However, pursuant to the proposed rule change, DTC would modify these concepts and certain associated processes to more closely align with the analogous proposed loss allocation provisions in proposed Rule 4 (e.g., Loss Allocation Notice, Loss Allocation Termination Notification Period, and Loss Allocation Cap).

²⁰ Rule 4, Section 4(a)(1), *supra* note 5. DTC has determined that this option is unnecessary because, in practice, DTC would never have liability under a Clearing Agency Agreement that exceeds the excess assets of the Participant that defaulted.

²¹DTC believes that this change would provide an objective date that is more appropriate for the application of the Participants Fund to complete settlement, because the "time the loss or liability was discovered" would necessarily have to be the day the Participants Fund was applied to complete settlement.

for the election to terminate from ten (10) Business Days to five (5) Business Days,²² and would also change the beginning date of such notification period from the receipt of the notice to the date of the issuance of the Settlement Charge Notice. 23 A Participant that elects to terminate its business with DTC would, subject to its cap, remain responsible for (i) its pro rata settlement charge that was the subject of the Settlement Charge Notice and (ii) all other pro rata settlement charges until the Participant Termination Date (as defined below and in the proposed rule change). The proposed cap on pro rata settlement charges of a Participant that has timely notified DTC of its election to terminate its business with DTC would be the amount of its Aggregate Required Deposit and Investment, as fixed on the day of the pro rata settlement charge that was the subject of the Settlement Charge Notice, plus 100% of the amount thereof ("Settlement Charge Cap"). The proposed Settlement Charge Cap would be no greater than the current cap.²⁴

The pro rata application of the Actual Participants Fund Deposits of non-defaulting Participants to complete settlement when there is a Participant Default is not the allocation of a loss. A pro rata settlement charge would relate solely to the completion of settlement. New proposed loss allocation concepts described below, including, but not limited to, a "round," "Event Period," and "Corporate Contribution," would not apply to pro rata settlement charges.²⁵

²² DTC believes this shorter period would be sufficient for a Participant to decide whether to give notice to terminate its business with DTC in response to a settlement charge. In addition, a five (5) Business Day pro rata settlement charge notification period would conform to the proposed loss allocation notification period in this proposed rule change and in the proposed rule changes for

NSCC and FICC. See infra note 37.

B. Changes To Enhance Resiliency of DTC's Loss Allocation Process

In order to enhance the resiliency of DTC's loss allocation process and to align, to the extent practicable and appropriate, its loss allocation approach to that of the other DTCC Clearing Agencies, DTC proposes to introduce certain new concepts and to modify other aspects of its loss allocation waterfall. The proposed rule change would adopt an enhanced allocation approach for losses, whether arising from Default Loss Events or Declared Non-Default Loss Events (as defined below and in the proposed rule change). In addition, the proposed rule change would clarify the loss allocation process as it relates to losses arising from or relating to multiple default or nondefault events in a short period of time.

Accordingly, DTC is proposing four (4) key changes to enhance DTC's loss allocation process:

(1) Mandatory Corporate Contribution

Current Section 4 of Rule 4 provides that if there is an unsatisfied loss or liability, DTC may, in its sole discretion and in such amount as DTC would determine, "charge the existing retained earnings and undivided profits" of DTC.

Under the proposed rule change, DTC would replace the discretionary application of an unspecified amount of retained earnings and undivided profits with a mandatory, defined Corporate Contribution (as defined below and in the proposed rule change). The Corporate Contribution would be used for losses and liabilities that are incurred by DTC with respect to an

also a remedial provision for a Participant Default when, additionally, DTC ceases to act for the Participant and there are remaining losses or liabilities. If a Participant Default occurs, the application of proposed Section 3 would be required, the application of proposed Section 4 would be at the discretion of DTC. Whether or not proposed Section 4 has been applied, once there is a loss due to a Participant Default and DTC ceases to act for the Participant, proposed Section 5 would apply. See supra note 10.

A principal type of Participant Default is a failure to settle. A Participant's obligation to pay any amount due in settlement is secured by Collateral of the Participant. When the Defaulting Participant fails to pay its settlement obligation, under Rule 9(B), Section 2, DTC has the right to Pledge or sell such Collateral to satisfy the obligation. Supra note 5. (It is more likely that DTC would borrow against the Collateral to complete settlement on the Business Day, because it is unlikely to be able to liquidate Collateral for same day funds in time to settle on that Business Day.) If DTC Pledges the Collateral to secure a loan to fund settlement (e.g., under the End-of-Day Credit Facility), the Collateral would have to be sold to obtain funds to repay the loan. In any such sale of the Collateral, there is a risk, heightened in times of market stress, that the proceeds of the sale would be insufficient to repay the loan. That deficiency would be a liability or loss to which proposed Section 5 of Rule 4 would apply, i.e., a Default Loss Event.

Event Period (as defined below and in the proposed rule change), whether arising from a Default Loss Event or Declared Non-Default Loss Event, before the allocation of losses to Participants.

The proposed "Corporate Contribution" would be defined to be an amount equal to fifty percent (50%) of DTC's General Business Risk Capital Requirement.²⁶ DTC's General Business Risk Capital Requirement, as defined in DTC's Clearing Agency Policy on Capital Requirements,²⁷ is, at a minimum, equal to the regulatory capital that DTC is required to maintain in compliance with Rule 17Ad-22(e)(15) under the Securities Exchange Act of 1934, as amended (the "Act").28 The proposed Corporate Contribution would be held in addition to DTC's General Business Risk Capital Requirement.

The proposed Corporate Contribution would apply to losses arising from Default Loss Events and Declared Non-Default Loss Events, and would be a mandatory contribution of DTC prior to any allocation among Participants.²⁹ As proposed, if the proposed Corporate Contribution is fully or partially used against a loss or liability relating to an Event Period, the Corporate Contribution would be reduced to the remaining unused amount, if any, during the following two hundred fifty (250) Business Days in order to permit DTC to replenish the Corporate Contribution.³⁰ To ensure transparency, Participants would receive notice of any such reduction to the Corporate Contribution.

By requiring a defined contribution of DTC corporate funds towards losses and

²³ DTC believes that setting the start date of the notification period to an objective date would enhance transparency and provide a common timeframe to all affected Participants.

²⁴ Current Section 8 of Rule 4 provides for a cap that is equal to the greater of (a) the amount of its Aggregate Required Deposit and Investment, as fixed immediately prior to the time of the first pro rata charge, plus 100% of the amount thereof, or (b) the amount of all prior pro rata charges attributable to the same loss or liability with respect to which the Participant has not timely exercised its right to limit its obligation as provided above. *Supra* note 5. The alternative limit in clause (b) would be eliminated in proposed Section 8(a) in favor of a single defined standard.

²⁵ Proposed Sections 3, 4 and 5 of Rule 4 together relate, in whole or in part, to what may happen when there is a Participant Default. Proposed Section 3 is the basic provision of remedies if a Participant fails to satisfy an obligation to DTC. Proposed Section 4 is a specific remedy for a failure to settle by a Defaulting Participant, *i.e.*, a specific type of Participant Default. Proposed Section 5 is

²⁶ DTC calculates its General Business Risk Capital Requirement as the amount equal to the greatest of (i) an amount determined based on its general business profile, (ii) an amount determined based on the time estimated to execute a recovery or orderly wind-down of DTC's critical operations, and (iii) an amount determined based on an analysis of DTC's estimated operating expenses for a six (6) month period.

²⁷ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR–DTC–2017–003).

²⁸ 17 CFR 240.17Ad-22(e)(15).

²⁹ The proposed rule change would not require a Corporate Contribution with respect to a pro rata settlement charge. However, as discussed above, if, after a Participant Default, the proceeds of the sale of the Collateral of the Participant are insufficient to repay the lenders under the End-of-Day Credit Facility, and DTC has ceased to act for the Participant, the shortfall would be a loss arising from a Default Loss Event, subject to the Corporate Contribution.

³⁰ DTC believes that two hundred fifty (250) Business Days would be a reasonable estimate of the time frame that DTC would require to replenish the Corporate Contribution by equity in accordance with DTC's Clearing Agency Policy on Capital Requirements, including a conservative additional period to account for any potential delays and/or unknown exigencies in times of distress.

liabilities arising from Default Loss Events and Declared Non-Default Loss Events, the proposed rule change would limit Participant obligations to the extent of such Corporate Contribution and thereby provide greater clarity and transparency to Participants as to the calculation of their exposure to losses and liabilities.

Proposed Rule 4 would also further clarify that DTC can voluntarily apply amounts greater than the Corporate Contribution against any loss or liability (including non-default losses) of DTC, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation existing at the time.

The proposed rule changes relating to the calculation and mandatory application of the Corporate Contribution are set forth in proposed Section 5 of Rule 4.

(2) Introducing an Event Period

The proposed rule change would clearly define the obligations of DTC and its Participants regarding the allocation of losses or liabilities relating to or arising out of a Default Loss Event or a Declared Non-Default Loss Event. The proposed rule change would define "Default Loss Event" as the determination by DTC to cease to act for a Participant pursuant to Rule 10, Rule 11, or Rule 12 (such Participant, a "CTA Participant"). "Declared Non-Default Loss Event" would be defined as the determination by the Board of Directors that a loss or liability incident to the clearance and settlement business of DTC may be a significant and substantial loss or liability that may materially impair the ability of DTC to provide clearance and settlement services in an orderly manner and will potentially generate losses to be mutualized among Participants in order to ensure that DTC may continue to offer clearance and settlement services in an orderly manner. In order to balance the need to manage the risk of sequential loss events against Participants' need for certainty concerning maximum loss allocation exposures, DTC is proposing to introduce the concept of an "Event Period" to address the losses and liabilities that may arise from or relate to multiple Default Loss Events and/or Declared Non-Default Loss Events that arise in quick succession. Specifically, the proposal would group Default Loss Events and Declared Non-Default Loss Events occurring in a period of ten (10) Business Days ("Event Period") for purposes of allocating losses to Participants in one or more rounds, subject to the limits of loss allocation set

forth in the proposed rule change and as explained below.³¹ In the case of a loss or liability arising from or relating to a Default Loss Event, an Event Period would begin on the day on which DTC notifies Participants that it has ceased to act for a Participant (or the next Business Day, if such day is not a Business Day). In the case of a Declared Non-Default Loss Event, the Event Period would begin on the day that DTC notifies Participants of the Declared Non-Default Loss Event (or the next Business Day, if such day is not a Business Day). If a subsequent Default Loss Event or Declared Non-Default Loss Event occurs within the Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period. An Event Period may include both Default Loss Events and Declared Non-Default Loss Events, and there would not be separate Event Periods for Default Loss Events or Declared Non-Default Loss Events occurring within overlapping ten (10) Business Day periods.

The amount of losses that may be allocated by DTC, subject to the required Corporate Contribution, and to which a Loss Allocation Cap would apply for any Participant that elects to terminate its business with DTC in respect of a loss allocation round, would include any and all losses from any Default Loss Events and any Declared Non-Default Loss Events during the Event Period, regardless of the amount of time, during or after the Event Period, required for such losses to be crystallized and allocated. 32

The proposed rule changes relating to the implementation of an Event Period are set forth in proposed Section 5 of Rule 4.

(3) Introducing the Concept of "Rounds" and Loss Allocation Notice

Pursuant to the proposed rule change, a loss allocation "round" would mean a

series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the sum of the Loss Allocation Caps of affected Participants (a "round cap"). When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. DTC would continue the loss allocation process in successive rounds until all losses from the Event Period are allocated among Participants that have not submitted a Termination Notice (as defined below and in the proposed rule change) in accordance with proposed

Section 6(b) of Rule 4.

Each loss allocation would be communicated to Participants by the issuance of a notice that advises each Participant of the amount being allocated to it (each, a "Loss Allocation Notice"). The calculation of each Participant's pro rata allocation charge would be similar to the current Section 4 calculation of a pro rata charge except that, for greater simplicity, it would not include the current distinction for common members of another clearing agency pursuant to a Clearing Agency Agreement.³³ In addition, for enhanced clarity as to the date of determination of the ratio, it would be based on the Required Participants Fund Deposits as fixed on the first day of the Event Period, as opposed to the current language "at the time the loss or liability was discovered." 34

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. Participants would receive two (2) Business Days' notice of a loss allocation,³⁵ and Participants would be required to pay the requisite amount no later than the second Business Day following the issuance of such notice.36

Continued

³¹ DTC believes that having a ten (10) Business Day Event Period would provide a reasonable period of time to encompass potential sequential Default Loss Events and/or Declared Non-Default Loss Events that are likely to be closely linked to an initial event and/or a severe market dislocation episode, while still providing appropriate certainty for Participants concerning their maximum exposure to allocated losses with respect to such events.

 $^{^{\}rm 32}\,\mathrm{As}$ discussed below, each Participant that is a Participant on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Default Loss Event (other than a Default Loss Event with respect to which it is the CTA Participant) and each Declared Non-Default Loss Event occurring during the Event Period.

³³ See supra note 20.

³⁴ DTC believes that this change would provide an objective date that is appropriate for the new proposed loss allocation process, which would be designed to allocate aggregate losses relating to an Event Period, rather than one loss at a time.

³⁵ DTC believes allowing Participants two (2) Business Days to satisfy their loss allocation obligations would provide Participants sufficient notice to arrange funding, if necessary, while allowing DTC to address losses in a timely manner.

³⁶ Current Section 4 of Rule 4 provides that if the Participants Fund is applied to a loss or liability, DTC must notify each Participant of the charge and the reasons therefor. Proposed Section 5 would modify this process to (i) require DTC to give prior notice; and (ii) require Participants to pay loss allocation charges, rather than directly charging their Required Participants Fund Deposits. DTC believes that shifting from the two-step methodology of applying the Participants Fund and then requiring Participants to immediately

Multiple Loss Allocation Notices may be issued with respect to each round, up to the round cap.

The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Participant in that round has five (5) Business Days 37 from the issuance 38 of such first Loss Allocation Notice for the round (such period, a "Loss Allocation Termination Notification Period'') to notify DTC of its election to terminate its business with DTC (such notification, whether with respect to a Settlement Charge Notice or Loss Allocation Notice, a "Termination Notice") pursuant to proposed Section 8(b) of Rule 4 and thereby benefit from its Loss Allocation Cap.

The round cap of any second or subsequent round may differ from the first or preceding round cap because there may be fewer Participants in a second or subsequent round if Participants elect to terminate their business with DTC as provided in proposed Section 8(b) of Rule 4 following the first Loss Allocation Notice in any round.

For example, for illustrative purposes only, after the required Corporate Contribution, if DTC has a \$4 billion loss determined with respect to an Event Period and the sum of Loss Allocation Caps for all Participants

replenish it to requiring direct payment would increase efficiency, while preserving the right to charge the Settlement Account of the Participant in the event the Participant doesn't timely pay. Such a failure to pay would be, self-evidently, a Participant Default, triggering recourse to the Actual Participants Fund Deposit of the Participant under proposed Section 3 of Rule 4. In addition, this change would provide greater stability for DTC in times of stress by allowing DTC to retain the Participants Fund, its critical pre-funded resource, while charging loss allocations. DTC believes doing so would allow DTC to retain the Participants Fund as a liquidity resource which may be applied to fund settlement among non-defaulting Participants, if a Defaulting Participant fails to settle. By being able to manage its liquidity resources throughout the loss allocation process, DTC would be able to continue to provide its critical operations and services during what would be expected to be a

subject to the loss allocation is \$3 billion, the first round would begin when DTC issues the first Loss Allocation Notice for that Event Period. DTC could issue one or more Loss Allocation Notices for the first round until the sum of losses allocated equals \$3 billion. Once the \$3 billion is allocated, the first round would end and DTC would need a second round in order to allocate the remaining \$1 billion of loss. DTC would then issue a Loss Allocation Notice for the \$1 billion and this notice would be the first Loss Allocation Notice for the second round. The issuance of the Loss Allocation Notice for the \$1 billion would begin the second round.

The proposed rule change would link the Loss Allocation Cap to a round in order to provide Participants the option to limit their loss allocation exposure at the beginning of each round. As proposed, a Participant could limit its loss allocation exposure to its Loss Allocation Cap by providing notice of its election to terminate its business with DTC within five (5) Business Days after the issuance of the first Loss Allocation Notice in any round.

The proposed rule changes relating to the implementation of "rounds" and Loss Allocation Notices are set forth in proposed Section 5 of Rule 4.

(4) Capping Terminating Participants' Loss Allocation Exposure and Related Changes

As discussed above, the proposed rule change would continue to provide Participants the opportunity to limit their loss allocation exposure by offering a termination option; however, the associated termination process would be modified.

As proposed, if a Participant timely provides notice of its election to terminate its business with DTC as provided in proposed Section 8(b) of Rule 4, its maximum payment obligation with respect to any loss allocation round would be the amount of its Aggregate Required Deposit and Investment, as fixed on the first day of the Event Period, plus 100% of the amount thereof ("Loss Allocation Cap"),39 provided that the Participant complies with the requirements of the termination process in proposed Section 6(b) of Rule 4. DTC may retain the entire Actual Participants Fund Deposit of a Participant subject to loss allocation, up to the Participant's Loss Allocation Cap. If a Participant's Loss Allocation Cap exceeds the Participant's then-current

Required Participants Fund Deposit, it must still pay the excess amount.

As proposed, Participants would have five (5) Business Days from the issuance of the first Loss Allocation Notice in any round to decide whether to terminate its business with DTC, and thereby benefit from its Loss Allocation Cap. The start of each round 40 would allow a Participant the opportunity to notify DTC of its election to terminate its business with DTC after satisfaction of the losses allocated in such round.

Specifically, the first round and each subsequent round of loss allocation would allocate losses up to a round cap of the aggregate of all Loss Allocation Caps of those Participants included in the round. If a Participant provides notice of its election to terminate its business with DTC, it would be subject to loss allocation in that round, up to its Loss Allocation Cap. If the first round of loss allocation does not fully cover DTC's losses, a second round will be noticed to those Participants that did not elect to terminate in the previous round. As noted above, the amount of any second or subsequent round cap may differ from the first or preceding round cap because there may be fewer Participants in a second or subsequent round if Participants elect to terminate their business with DTC as provided in proposed Section 8(b) of Rule 4 following the first Loss Allocation Notice in any round.

Pursuant to the proposed rule change, in order to avail itself of its Loss Allocation Cap, the Participant would need to follow the requirements in proposed Section 6(b) of Rule 4. In addition to retaining the substance of the existing requirements for any termination that are set forth in current Section 6 of Rule 4, proposed Section 6 also would provide that a Participant that provides a Termination Notice in connection with a loss allocation must: (1) Specify in the Termination Notice an effective date of termination ("Participant Termination Date"), which date shall be no later than ten (10) Business Days following the last day of the applicable Loss Allocation Termination Notification Period; (2) cease all activities and use of the Corporation's services other than activities and services necessary to terminate the business of the Participant with DTC; and (3) ensure that all activities and use of DTC services by such Participant cease on or prior to the Participant Termination Date.

³⁷ Current Section 8 of Rule 4 provides that the time period for a Participant to give notice of its election to terminate its business with DTC in respect of a pro rata charge is ten (10) Business Days after receiving notice of a pro rata charge. DTC believes that it is appropriate to shorten such time period from ten (10) Business Days to five (5) Business Days because DTC needs timely notice of which Participants would not be terminating their business with DTC for the purpose of calculating the loss allocation for any subsequent round. DTC believes that five (5) Business Days would provide Participants with sufficient time to decide whether to cap their loss allocation obligations by terminating their business with DTC.

³⁸ See supra note 23.

 $^{^{39}}$ The alternative limit in clause (b) would be eliminated in proposed Section 8(b) in favor of a single defined standard. See supra note 24.

⁴⁰ i.e., a Participant will only have the opportunity to terminate after the first Loss Allocation Notice in any round, and not after each Loss Allocation Notice in any round.

The proposed rule changes are designed to enable DTC to continue the loss allocation process in successive rounds until all of DTC's losses are allocated. Until all losses related to an Event Period are allocated and paid, DTC may retain the entire Actual Participants Fund Deposit of a Participant subject to loss allocation, up to the Participant's Loss Allocation Cap.

The proposed rule changes relating to capping terminating Participants' loss allocation exposure and related changes to the termination process are set forth in proposed Sections 5, 6, and 8 of Rule 4.

C. Clarifying Changes Relating to Loss Allocation for Non-Default Events

The proposed rule changes are intended to make the provisions in the Rules governing loss allocation more transparent and accessible to Participants. In particular, DTC is proposing the following change relating to loss allocation to provide clarity around the governance for the allocation of losses arising from a non-default event.⁴¹

Currently, DTC can use the Participants Fund to satisfy losses and liabilities arising from a Participant Default or arising from an event that is not due to a Participant Default (*i.e.*, a non-default loss), provided that such loss or liability is incident to the business of DTC.⁴²

DTC is proposing to clarify the governance around non-default losses that would trigger loss allocation to Participants by specifying that the Board of Directors would have to determine that there is a non-default loss that may be a significant and substantial loss or liability that may materially impair the ability of DTC to provide clearance and settlement services in an orderly manner and will potentially generate losses to be mutualized among the Participants in order to ensure that DTC may continue to offer clearance and settlement services in an orderly manner. The proposed rule change would provide that DTC would then be required to promptly notify Participants of this determination, which is referred to in the proposed rule as a Declared Non-Default Loss Event, as discussed above

Finally, as previously discussed, pursuant to the proposed rule change, proposed Rule 4 would include language to clarify that (i) the Corporate Contribution would apply to losses or liabilities arising from a Default Loss Event or a Declared Non-Default Loss Event, and (ii) the loss allocation waterfall would be applied in the same manner regardless of whether a loss arises from a Default Loss Event or a Declared Non-Default Loss Event.

The proposed rule changes relating to Declared Non-Default Loss Events and Participants' obligations for such events are set forth in proposed Section 5 of Rule 4.

D. Loss Allocation Waterfall Comparison

The following example illustrates the differences between the current and proposed loss allocation provisions:

Assumptions:

- (i) Participant A defaults on a Business Day (Day 1). On the same day, DTC ceases to act for Participant A, and notifies Participants of the cease to act. After applying Participant A's Participants Fund and liquidating Participant A's Collateral, DTC has a loss of \$350 million.
- (ii) Participant X voluntarily retires from membership five Business Days after DTC ceases to act for Participant A (Day 6).
- (iii) Participant B defaults seven Business Days after DTC ceases to act for Participant A (Day 8). On the same day, DTC ceases to act for Participant B, and notifies Participants of the cease to act. After applying Participant B's Participants Fund and liquidating Participant B's Collateral, DTC has a loss of \$350 million.
- (iv) The current DTC loss allocation provisions do not require a corporate contribution. DTC may, in its sole discretion and in such amounts as DTC may determine, charge the existing retained earnings and undivided profits of DTC. For the purposes of this example, it is assumed that DTC has determined, in its discretion, that DTC will contribute 25% of its retained earnings and undivided profits. The amount of DTC's retained earnings and undivided profits is \$364 million.

(v) DTC's General Business Risk Capital Requirement is \$158 million. Current Loss Allocation:

Under the current loss allocation provisions, with respect to the losses arising out of Participant A's default, DTC will contribute \$91 million (\$364 million * 25%) from retained earnings and undivided profits, and then allocate the remaining loss of \$259 million (\$350 million - \$91 million) to Participants.

With respect to the losses arising out of Participant B's default, DTC will contribute \$68 million ((\$364 million – \$91 million) * 25%) from the balance of its retained earnings and undivided

profits, and then allocate the remaining loss of \$282 million (\$350 million – \$68 million) to Participants. Because Participant X voluntarily retired before DTC ceased to act for Participant B, Participant X is not subject to loss allocation with respect to losses arising out of Participant B's default.

Altogether, with respect to the losses arising out of defaults of Participant A and Participant B, DTC will contribute \$159 million of retained earnings and undivided profits, and will allocate losses of \$541 million to Participants.

Proposed Loss Allocation:

Under the proposed loss allocation provisions, a Default Loss Event with respect to Participant A's default would have occurred on Day 1, and a Default Loss Event with respect to Participant B's default would have occurred on Day 8. Because the Default Loss Events occurred during a 10-Business Day period they would be grouped together into an Event Period for purposes of allocating losses to Participants. The Event Period would begin on the 1st Business Day and end on the 10th Business Day.

With respect to losses arising out of Participant A's default, DTC would apply a Corporate Contribution of \$79 million (\$158 million * 50%) and then allocate the remaining loss of \$271 million (\$350 million - \$79 million) to Participants. With respect to losses arising out of Participant B's default, DTC would not apply a Corporate Contribution since it would have already contributed the maximum Corporate Contribution of 50% of its General Business Risk Capital Requirement. DTC would allocate the loss of \$350 million arising out of Participant B's default to Participants. Because Participant X was a Participant on the first day of the Event Period, it would be subject to loss allocation with respect to all events occurring during the Event Period, even if the event occurred after its retirement. Therefore, Participant X would be subject to loss allocation with respect to Participant B's default.

Altogether, with respect to the losses arising out of defaults of Participant A and Participant B, DTC would apply a Corporate Contribution of \$79 million and allocate losses of \$621 million to Participants.

The principal differences in the above example are due to: (i) The proposed changes to the calculation and application of Corporate Contribution, and (ii) the proposed introduction of an Event Period.

⁴¹Non-default losses may arise from events such as damage to physical assets, a cyber-attack, or custody and investment losses.

⁴² See supra note 11.

E. Clarifying Changes Regarding Voluntary Retirement

Section 1 of Rule 2 provides that a Participant may terminate its business with DTC by notifying DTC in the appropriate manner. 43 To provide additional transparency to Participants with respect to the voluntary retirement of a Participant, and to align, where appropriate, with the proposed rule changes of NSCC and FICC with respect to voluntary termination, DTC is proposing to add proposed Section 6(a) to Rule 4, which would be titled, "Upon Any Voluntary Retirement." Proposed Section 6(a) of Rule 4 would (i) clarify the requirements 44 for a Participant that wants to voluntarily terminate its business with DTC, and (ii) address the situation where a Participant submits a Voluntary Retirement Notice (defined below) and subsequently receives a Settlement Charge Notice or the first Loss Allocation Notice in a round on or prior to the Voluntary Retirement Date (defined below).

Specifically, DTC is proposing that if a Participant elects to terminate its business with DTC pursuant to Section 1 of Rule 2 for reasons other than those specified in proposed Section 8 (a "Voluntary Retirement"), the Participant would be required to:

(1) Provide a written notice of such termination to DTC ("Voluntary Retirement Notice"), as provided for in Section 1 of Rule 2;

(2) specify in the Voluntary Retirement Notice a desired date for the termination of its business with DTC ("Voluntary Retirement Date");

(3) cease all activities and use of DTC services other than activities and services necessary to terminate the business of the Participant with DTC; and

(4) ensure that all activities and use of DTC services by the Participant cease on

or prior to the Voluntary Retirement Date.⁴⁵

Proposed Section 6(a) of Rule 4 would provide that if the Participant fails to comply with the requirements of proposed Section 6(a), its Voluntary Retirement Notice would be deemed void.⁴⁶

Further, proposed Section 6(a) of Rule 4 would provide that if a Participant submits a Voluntary Retirement Notice and subsequently receives a Settlement Charge Notice or the first Loss Allocation Notice in a round on or prior to the Voluntary Retirement Date, such Participant must timely submit a Termination Notice in order to benefit from its Settlement Charge Cap or Loss Allocation Cap, as the case may be. In such a case, the Termination Notice would supersede and void the pending Voluntary Retirement Notice submitted by the Participant.

F. Changes to the Retention Time for the Actual Participants Fund Deposit of a Former Participant

Current Rule 4 provides that after three months from when a Person has ceased to be a Participant, DTC shall return to such Person (or its successor in interest or legal representative) the amount of the Actual Participants Fund Deposit of the former Participant plus accrued and unpaid interest to the date of such payment (including any amount added to the Actual Participants Fund Deposit of the former Participant through the sale of the Participant's Preferred Stock), provided that DTC receives such indemnities and guarantees as DTC deems satisfactory with respect to the matured and contingent obligations of the former Participant to DTC. Otherwise, within four years after a Person has ceased to be a Participant, DTC shall return to such Person (or its successor in interest or legal representative) the amount of the Actual Participants Fund Deposit of the former Participant plus accrued and unpaid interest to the date of such payment, except that DTC may offset against such payment the amount of any known loss or liability to DTC arising out of or related to the obligations of the former Participant to DTC.

DTC is proposing to reduce the time, after a Participant ceases to be a Participant, at which DTC would be required to return the amount of the Actual Participants Fund Deposit of the former Participant plus accrued and unpaid interest, whether the Participant ceases to be such because it elected to terminate its business with DTC in response to a Settlement Charge Notice or Loss Allocation Notice or otherwise. Pursuant to the proposed rule change, the time period would be reduced from four (4) years to two (2) years. All other requirements relating to the return of the Actual Participants Fund Deposit would remain the same.

The four (4) year retention period was implemented at a time when there were more deposits and processing of physical certificates, as well as added risks related to manual processing, and related claims could surface many years after an alleged event. DTC believes that the change to two (2) years is appropriate because, currently, as DTC and the industry continue to move toward automation and dematerialization, claims typically surface more quickly. Therefore, DTC believes that a shorter retention period of two (2) years would be sufficient to maintain a reasonable level of coverage for possible claims arising in connection with the activities of a former Participant, while allowing DTC to provide some relief to former Participants by returning their Actual Participants Fund Deposits more quickly.

(ii) Proposed Rule Changes

The foregoing changes as well as other changes (including a number of technical and conforming changes) that DTC is proposing in order to improve the transparency and accessibility of Rule 4 are described in detail below.

A. Changes Relating to Participant Default, Pro Rata Settlement Charges and Loss Allocation

Section 3

As discussed above, current Section 3 of Rule 4 provides that, if a Participant fails to satisfy an obligation to DTC, DTC may, in such order and in such amounts as DTC determines, apply the Actual Participants Fund Deposit of the defaulting Participant, Pledge the shares of Preferred Stock of the defaulting

⁴³ Section 1 of Rule 2 provides, in relevant part, that "[a] Participant may terminate its business with the Corporation by notifying the Corporation as provided in Sections 7 or 8 of Rule 4 or, if for a reason other than those specified in said Sections 7 and 8, by notifying the Corporation thereof; the Participant shall, upon receipt of such notice by the Corporation, cease to be a Participant. In the event that a Participant shall cease to be a Participant, the Corporation shall thereupon cease to make its services available to the Participant, except that the Corporation may perform services on behalf of the Participant or its successor in interest necessary to terminate the business of the Participant or its successor with the Corporation, and the Participant or its successor shall pay to the Corporation the fees and charges provided by these Rules with respect to services performed by the Corporation subsequent to the time when the Participant ceases to be a Participant." Supra note 5. DTC is proposing to modify the provision to clarify that the termination would be subject to proposed Section 6 of Rule 4.

 $^{^{\}rm 44}\,\rm The$ requirements would reflect current practice.

⁴⁵Typically, a Participant would ultimately submit a notice after having ceased its transactions and transferred all securities out of its Account.

⁴⁶ The purpose of this proposed provision is to clarify that a failure of a Participant to comply with proposed Section 6(a) of Rule 4 would mean that the Participant would continue to be a Participant. as if the Voluntary Retirement Notice had not been received by DTC. For example, Participant A submits a Voluntary Retirement Notice to DTC on April 1st and indicates a Voluntary Retirement Date of April 15th, but fails to comply with the requirements of proposed Section 6(a) of Rule 4 by the Voluntary Retirement Date. The Participant would continue to be a Participant after the Voluntary Retirement Date. If an Event Period subsequently occurs before the Participant submits a new Voluntary Retirement Notice and voluntarily retires in compliance with proposed Section 6(a), such Participant would be obligated to pay its pro rata shares of losses and liabilities arising from that Event Period.

Participant to its lenders as collateral security for a loan, and/or sell the shares of Preferred Stock of the defaulting Participant to other Participants.
Pursuant to the proposed rule change, Section 3 would retain most of these provisions, with the following modifications:

DTC proposes to add the term "Participant Default" in proposed Section 3 as a defined term for the failure of a Participant to satisfy an obligation to DTC, for drafting clarity and use in related provisions. The proposed rule change would reflect that the defined term "Participant Default," referring to the failure of a Participant to satisfy any obligation to DTC, includes the failure of a Defaulting Participant to satisfy its obligations as provided in Rule 9(B). In addition, the proposed rule change clarifies that, in the case of a Participant Default, DTC would first apply the Actual Participants Fund Deposit of the Participant to any unsatisfied obligations, before taking any other actions. This proposed clarification would reflect the current practice of DTC, and would provide Participants with enhanced transparency into the actions DTC would take with respect to the Participants Fund deposits and Participants Investment of a Participant that has failed to satisfy its obligations to DTC.

DTC proposes to correct the term "End-of-Day Facility," to the existing defined term "End-of-Day Credit Facility." DTC further proposes to clarify that, if DTC Pledges some or all of the shares of Preferred Stock of a Participant to its lenders as collateral security for a loan under the End-of-Day Credit Facility, DTC would apply the proceeds of such loan to the obligation the Participant had failed to satisfy, which is not expressly stated in current Section 3 of Rule 4.

In addition, DTC is proposing to make three ministerial changes to enhance readability by: (i) Removing the duplicative "in," in the phrase "in such order and in such amounts," (ii) replacing the word "eliminate" with "satisfy," and (iii) to conform to proposed changes, renumbering the list of actions that DTC may take when there is a Participant Default.

DTC is also proposing to add the heading "Application of Participants Fund Deposits and Preferred Stock Investments to Participant Default" to Section 3.

Section 4 and Section 5

As noted above, current Section 4 of Rule 4 provides that if DTC incurs a loss or liability which is not satisfied by

charging the Participant responsible for the loss pursuant to Section 3 of Rule 4, then DTC may, in any order and in any amount as DTC may determine, in its sole discretion, to the extent necessary to satisfy such loss or liability, ratably apply some or all of the Actual Participants Fund Deposits of all other Participants to such loss or liability and/ or charge the existing retained earnings and undivided profits of DTC. This provision relates to losses and liabilities that may be due to the failure of a Participant to satisfy obligations to DTC, if the Actual Participants Fund Deposit of that Participant does not fully satisfy the obligation, or to losses and liabilities for which no single Participant is obligated, *i.e.*, a "non-default loss." As discussed above, current Rule 4

currently provides a single set of tools and common processes for using the Participants Fund as both a liquidity resource and for the satisfaction of other losses and liabilities. The proposed rule change would provide separate liquidity and loss allocation provisions. More specifically, proposed Section 4 of Rule 4 would reflect the process for a "pro rata settlement charge," the application of the Actual Participants Fund Deposits of non-defaulting Participants for liquidity purposes in order to complete settlement, when a Defaulting Participant fails to satisfy its settlement obligation and the amount charged to its Actual Participants Fund Deposit by DTC pursuant to Section 3 of Rule 4 is insufficient to complete settlement. Proposed Section 5 of Rule 4 would contain the proposed loss allocation provisions.

Proposed Section 4

Pursuant to the proposed rule change, current Section 4 would be replaced in its entirety by proposed Section 4, and titled "Application of Participants Fund Deposits of Non-Defaulting Participants." First, for clarity, proposed Section 4 would expressly state that "[t]he Participants Fund shall constitute a liquidity resource which may be applied by the Corporation in such amounts as the Corporation shall determine, in its sole discretion, to fund settlement if there is a Defaulting Participant and the amount charged to the Actual Participants Fund Deposit of the Defaulting Participant pursuant to Section 3 of this Rule is not sufficient to complete settlement. In that case, the Corporation may apply the Actual Participants Fund Deposits of Participants other than the Defaulting Participant (each, a "non-defaulting Participant") as provided in this Section and/or apply such other liquidity resources as may be available to the

Corporation from time to time, including the End-of-Day Credit Facility."

Proposed Section 4 would retain the current principle that DTC must notify Participants and the Commission when it applies the Participants Fund deposits of non-defaulting Participants, by stating that if the Actual Participants Fund Deposits of non-defaulting Participants are applied to complete settlement, DTC must promptly notify each Participant and the Commission of the amount of the charge and the reasons therefor, and would define such notice as a Settlement Charge Notice.

Proposed Section 4 would retain the current calculation of pro rata charges by providing that each non-defaulting Participant's pro rata share 47 of any such application of the Participants Fund, defined as a "pro rata settlement charge," would be equal to (i) its Required Participants Fund Deposit, as such Required Participants Fund Deposit was fixed on the Business Day of such application 48 less its Additional Participants Fund Deposit, if any, on that day, divided by (ii) the sum of the Required Participants Fund Deposits of all non-defaulting Participants, as such Required Participants Fund Deposits were fixed on that day, less the sum of the Additional Participants Fund Deposits, if any, of such non-defaulting Participants on that day.

Proposed Section 4 would also provide a period of time within which a Participant could notify DTC of its election to terminate its business with DTC and thereby cap its liability, by providing that a Participant would have a period of five (5) Business Days following the issuance of a Settlement Charge Notice ("Settlement Charge Termination Notification Period") to notify DTC of its election to terminate its business with DTC pursuant to proposed Section 8(a), and thereby benefit from its Settlement Charge Cap, as set forth in proposed Section 8(a).49 Proposed Section 4 would also require that any Participant that gives DTC notice of its election to terminate its business with DTC must comply with proposed Section 6(b) of Rule 4,50 and if it does not, its election to terminate would be deemed void.

Proposed Section 4 would further provide that DTC may retain the entire amount of the Actual Participants Fund Deposit of a Participant subject to a pro rata settlement charge, up to the amount of the Participant's Settlement Charge

⁴⁷ See supra note 20.

⁴⁸ See supra note 21.

⁴⁹ See supra note 22.

⁵⁰ Proposed Section 6(b) is discussed below.

Cap in accordance with proposed Section 8(a) of Rule 4.

Current Section 5 of Rule 4 provides that "[e]xcept as provided in Section 8 of this Rule, if a pro rata charge is made pursuant to Section 4 of the current Rule against the Required Participants Fund Deposit of a Participant, and, as a consequence, the Actual Participants Fund Deposit of such Participant is less than its Required Participants Fund Deposit, the Participant shall, upon the demand of the Corporation, within such time as the Corporation shall require, Deposit to the Participants Fund the amount in cash needed to eliminate any resulting deficiency in its Required Participants Fund Deposit. If the Participant shall fail to make such deposit to the Participants Fund, the Corporation may take disciplinary action against the Participant pursuant to these Rules. Any disciplinary action which the Corporation takes pursuant to these Rules, or the voluntary or involuntary cessation of participation by the Participant, shall not affect the obligations of the Participant to the Corporation or any remedy to which the Corporation may be entitled under applicable law.'

Proposed Section 4 would incorporate current Section 5 of Rule 4, modified as follows: (i) Conformed to reflect the consolidation of Section 5 into proposed Section 4, (ii) replacement of "Except as provided in" with "Subject to," to harmonize with language used elsewhere in proposed Rule 4, and (iii) corrections of two typographical errors, in order to accurately reflect that the Actual Participants Fund Deposit of a Participant would be applied, and not the Required Participants Fund Deposit, and to capitalize the word "deposit" because it is a defined term.

Proposed Section 5

Proposed Section 5 of Rule 4 would address the substantially new and revised proposed loss allocation, which would apply to losses and liabilities relating to or arising out of a Default Loss Event or a Declared Non-Default Loss Event. Pursuant to the proposed rule change, DTC would restructure and modify its existing loss allocation waterfall as described below. The heading "Loss Allocation Waterfall" would be added to proposed Section 5.

Proposed Section 5 would establish the concept of an "Event Period" to provide for a clear and transparent way of handling multiple loss events occurring in a period of ten (10) Business Days, which would be grouped into an Event Period. As stated above, both Default Loss Events and Declared Non-Default Loss Events could occur within the same Event Period.

The Event Period with respect to a Default Loss Event would begin on the day on which DTC notifies Participants that it has ceased to act for the Participant (or the next Business Day, if such day is not a Business Day). In the case of a Declared Non-Default Loss Event, the Event Period would begin on the day that DTC notifies Participants of the Declared Non-Default Loss Event (or the next Business Day, if such day is not a Business Day). Proposed Section 5 would provide that if a subsequent Default Loss Event or Declared Non-Default Loss Event occurs during an Event Period, any losses or liabilities arising out of or relating to any such subsequent event would be resolved as losses or liabilities that are part of the same Event Period, without extending the duration of such Event Period.

As proposed, each CTA Participant would be obligated to DTC for the entire amount of any loss or liability incurred by DTC arising out of or relating to any Default Loss Event with respect to such CTA Participant. Under the proposal, to the extent that such loss or liability is not satisfied pursuant to proposed Section 3 of Rule 4, DTC would apply a Corporate Contribution thereto and charge the remaining amount of such loss or liability as provided in proposed Section 5

Section 5. Under proposed Section 5, the loss allocation waterfall would begin with a new mandatory Corporate Contribution from DTC. Rule 4 currently provides that the use of any retained earnings and undivided profits by DTC is a voluntary contribution of a discretionary amount of its retained earnings. Proposed Section 5 of Rule 4 would, instead, require a defined corporate contribution to losses and liabilities that are incurred by DTC with respect to an Event Period. As proposed, the Corporate Contribution to losses or liabilities that are incurred by DTC with respect to an Event Period would be defined as an amount that is equal to fifty percent (50%) of the amount calculated by DTC in respect of its General Business Risk

Capital Requirement as of the end of the calendar quarter immediately preceding the Event Period.⁵¹ DTC's General Business Risk Capital Requirement, as defined in DTC's Clearing Agency Policy on Capital Requirements,⁵² is, at a minimum, equal to the regulatory capital that DTC is required to maintain in compliance with Rule 17Ad–22(e)(15) under the Act.⁵³

If DTC applies the Corporate Contribution to a loss or liability arising out of or relating to one or more Default Loss Events or Declared Non-Default Loss Events relating to an Event Period, then for any subsequent Event Periods that occur during the next two hundred fifty (250) Business Days, the Corporate Contribution would be reduced to the remaining unused portion of the Corporate Contribution amount that was applied for the first Event Period.⁵⁴ Proposed Section 5 would require DTC to notify Participants of any such reduction to the Corporate Contribution.

Proposed Section 5 of Rule 4 would provide that nothing in the Rules would prevent DTC from voluntarily applying amounts greater than the Corporate Contribution against any DTC loss or liability, if the Board of Directors, in its sole discretion, believes such to be appropriate under the factual situation

existing at the time.

Proposed Section 5 of Rule 4 would provide that DTC shall apply the Corporate Contribution to losses and liabilities that arise out of or relate to one or more Default Loss Events and/or Declared Non-Default Loss Events that occur within an Event Period. The proposed rule change also provides that if losses and liabilities with respect to such Event Period remain unsatisfied following application of the Corporate Contribution, DTC would allocate such losses and liabilities to Participants, as described below.

Proposed Section 5 of Rule 4 would state that each Participant that is a Participant on the first day of an Event Period would be obligated to pay its pro rata share of losses and liabilities arising out of or relating to each Default Loss Event (other than a Default Loss Event with respect to which it is the CTA Participant) and each Declared Non-Default Loss Event occurring during the Event Period. In addition, proposed Section 5 of Rule 4 would make it clear that any CTA Participant for which DTC ceases to act on a non-Business Day, triggering an Event Period that commences on the next Business Day, would be deemed to be a Participant on the first day of that Event Period. In addition, DTC is proposing to clarify that after a first round of loss allocations with respect to an Event Period, only Participants that have not submitted a Termination Notice in accordance with proposed Section 6(b) of Rule 4 would be subject to loss allocations with respect to subsequent rounds relating to that Event Period. The proposed change would also provide that DTC may retain the entire Actual Participants Fund

⁵¹ See supra note 26.

⁵² See supra note 27.

^{53 17} CFR 240.17Ad-22(e)(15).

⁵⁴ See supra note 30.

Deposit of a Participant subject to loss allocation, up to the Participant's Loss Allocation Cap in accordance with proposed Section 8(b) of Rule 4.

Pursuant to the proposed rule change, DTC would notify Participants subject to loss allocation of the amounts being allocated to them by a Loss Allocation Notice in successive rounds of loss allocations. Proposed Section 5 would state that a loss allocation "round" would mean a series of loss allocations relating to an Event Period, the aggregate amount of which is limited by the sum of the Loss Allocation Caps of affected Participants (a "round cap"). When the aggregate amount of losses allocated in a round equals the round cap, any additional losses relating to the applicable Event Period would be allocated in one or more subsequent rounds, in each case subject to a round cap for that round. DTC may continue the loss allocation process in successive rounds until all losses from the Event Period are allocated among Participants that have not submitted a Termination Notice in accordance with proposed Section 6(b) of Rule 4.

Each Loss Allocation Notice would specify the relevant Event Period and the round to which it relates. The first Loss Allocation Notice in any first, second, or subsequent round would expressly state that such Loss Allocation Notice reflects the beginning of the first, second, or subsequent round, as the case may be, and that each Participant in that round has five (5) Business Days from the issuance of such first Loss Allocation Notice for the round 55 to notify DTC of its election to terminate its business with DTC pursuant to proposed Section 8(b) of Rule 4, and thereby benefit from its Loss Allocation Cap. 56

Loss allocation obligations would continue to be calculated based upon a Participant's pro rata share of the loss. 57 As proposed, each Participant's pro rata share of losses and liabilities to be allocated in any round would be equal to (i) (A) its Required Participants Fund Deposit, as such Required Participants Fund Deposit was fixed on the first day of the Event Period,⁵⁸ less (B) its Additional Participants Fund Deposit, if any, on such day, divided by (ii) (A) the sum of the Required Participants Fund Deposits of all Participants subject to loss allocation in such round, as such Required Participants Fund Deposits were fixed on such day, less (B) the sum

of any Additional Participants Fund Deposits, if any, of all Participants subject to loss allocation in such round on such day.⁵⁹

As proposed, Participants would have two (2) Business Days after DTC issues a first round Loss Allocation Notice to pay the amount specified in any such notice. In contrast to the current Section 4, under which DTC may apply the Actual Participants Fund Deposits of Participants directly to the satisfaction of loss allocation amounts, under proposed Section 5, DTC would require Participants to pay their loss allocation amounts (leaving their Actual Participants Fund Deposits intact).60 On a subsequent round (i.e., if the first round did not cover the entire loss of the Event Period because DTC was only able to allocate up to the sum of the Loss Allocation Caps of those Participants included in the round), Participants would also have two (2) Business Days after notice by DTC to pay their loss allocation amounts (again subject to their Loss Allocation Caps), unless a Participant timely notified (or will timely notify) DTC of its election to terminate its business with DTC with respect to a prior loss allocation round.

Under the proposal, if a Participant fails to make its required payment in respect of a Loss Allocation Notice by the time such payment is due, DTC would have the right to proceed against such Participant as a Participant that has failed to satisfy an obligation in accordance with proposed Section 3 of Rule 4 described above. For additional clarity, proposed Section 5 of Rule 4 would state that all amounts due from a Participant pursuant to proposed Section 5 of Rule 4 may be debited from the Settlement Account of such Participant. Proposed Section 5 of Rule 4 would also provide that DTC may retain the entire Actual Participants Fund Deposit of a Participant subject to loss allocation, up to the Participant's Loss Allocation Cap in accordance with Section 8(b) of Rule 4. Participants that wish to terminate their business with DTC would be required to comply with the requirements in proposed Section 6(b) of Rule 4, described further below. Specifically, proposed Section 5 would provide that if, after notifying DTC of its election to terminate its business with DTC pursuant to proposed Section 8(b) of Rule 4, the Participant fails to comply with the provisions of proposed Section 6(b) of Rule 4, its notice of termination would be deemed void and any further losses resulting from the applicable

Event Period may be allocated against it as if it had not given such notice.

Section 6

Section 6 of Rule 4 currently provides that whenever a Participant ceases to be such, it continues to be obligated (a) to satisfy any deficiency in the amount of its Required Participants Fund Deposit and/or Required Preferred Stock Investment that it did not satisfy prior to such time, including (i) any deficiency resulting from a pro rata charge with respect to which the Participant has given notice to DTC of its election to terminate its business with DTC pursuant to Section 8 of Rule 4 and (ii) any deficiency the Participant is required to satisfy pursuant to Sections 3 (an obligation that a Participant failed to satisfy) or 5 (the requirement of a Participant to eliminate the deficiency in its Required Participants Fund Deposit) of Rule 4 and (b) to discharge any liability of the Participant to DTC resulting from the transactions of the Participant open at the time it ceases to be a Participant or on account of transactions occurring while it was a Participant.

The heading "Obligations of Participant Upon Termination" would be added to Section 6 of Rule 4. As discussed above, DTC is proposing to add proposed Section 6(a) to Rule 4, which would (i) clarify the requirements for the Voluntary Retirement of a Participant, and (ii) address the situation where a Participant submits a Voluntary Retirement Notice and subsequently receives a Settlement Charge Cap or the first Loss Allocation Notice in a round on or prior to the Voluntary Retirement Date. Proposed Section 6(a) of Rule 4 would also provide that if a Participant submits a Voluntary Retirement Notice and subsequently receives a Settlement Charge Notice or the first Loss Allocation Notice in a round on or prior to the Voluntary Retirement Date, such Participant must timely submit a Termination Notice in order to benefit from its Settlement Charge Cap or Loss Allocation Cap, respectively. In such a case, the Termination Notice would supersede and void the pending Voluntary Retirement Notice submitted by the Participant.

DTC is proposing to add Proposed Section 6(b), titled "Upon Termination Following Settlement Charge or Loss Allocation." Proposed Section 6(b) would state that if a Participant timely notifies DTC of its election to terminate its business with DTC in respect of a pro rata settlement charge as set forth in proposed Section 4 of Rule 4 or a loss allocation as set forth in proposed

 $^{^{55}}$ i.e., the Loss Allocation Termination Notification Period for that round.

⁵⁶ See supra note 37.

⁵⁷ See supra note 20.

⁵⁸ See supra note 21.

Ü

 $^{^{59}}$ See supra note 16. 60 See supra note 36.

Section 5 of Rule 4, defined as a "Termination Notice", the Participant would be required to: (1) Specify in the Termination Notice a Participant Termination Date, which date shall be no later than ten Business Davs following the last day of the applicable Settlement Charge Termination Notification Period or Loss Allocation Termination Notification Period; (2) cease all activities and use of the Corporation's services other than activities and services necessary to terminate the business of the Participant with DTC; and (3) ensure that all activities and use of DTC services by such Participant cease on or prior to the Participant Termination Date.

Proposed Section 6(b) of Rule 4 would provide that a Participant that terminates its business with DTC in compliance with proposed Section 6(b) would remain obligated for its pro rata share of losses and liabilities with respect to any Event Period for which it is otherwise obligated; however, its aggregate obligation would be limited to the amount of its Loss Allocation Cap (as fixed in the round for which it withdrew).

DTC is proposing to include a sentence in proposed Section 6(b) to make it clear that if the Participant fails to comply with the requirements set forth in this section, its Termination Notice will be deemed void, and the Participant will remain subject to further pro rata settlement charges pursuant to proposed Section 4 of Rule 4 or loss allocations pursuant to proposed Section 5 of Rule 4, as applicable, as if it had not given such notice.

For clarity, DTC is proposing to consolidate the requirements from current Section 6 of Rule 4 into proposed Section 6(c) of Rule 4, titled "After Any Termination," and modify them to conform to other proposed rule changes. In particular, DTC is proposing to clarify that a Participant that ceases to be such would continue to be subject to proposed Section 5 of Rule 4 for any Event Period for which it was a Participant on the first day of the Event Period. Proposed Section 6(c) of Rule 4 would state that whenever a Participant ceases to be such, it would continue to be obligated (i) to satisfy any deficiency in the amounts of its Required Participants Fund Deposit and/or Required Preferred Stock Investment that it did not satisfy prior to such time, including any deficiency the Participant is required to satisfy pursuant to proposed Sections 3 or 4 of Rule 4, (ii) subject to proposed Section 8, to satisfy any loss allocation pursuant to proposed Section 5 of Rule 4, and (iii) to

discharge any liability of the Participant to DTC resulting from the transactions of the Participant open at the time it ceases to be a Participant or on account of transactions occurring while it was a Participant.

Section 8

Pursuant to the proposed rule change, Section 8 would be titled "Termination; Obligation for Pro Rata Settlement Charges and Loss Allocations," and would be divided among proposed Section 8(a) "Settlement Charges," proposed Section 8(b) "Loss Allocations," proposed Section 8(c) "Maximum Obligation," and proposed Section 8(d) "Obligation to Replenish Deposit."

Pursuant to proposed Section 8(a), if a Participant, within five (5) Business Days after issuance of a Settlement Charge Notice pursuant to proposed Section 4 of Rule 4, gives notice to DTC of its election to terminate its business with DTC, the Participant would remain obligated for (i) its pro rata settlement charge that was the subject of such Settlement Charge Notice and (ii) all other pro rata settlement charges made by DTC until the Participant Termination Date. Subject to proposed Section 8(c), the terminating Participant's obligation would be limited to the amount of its Aggregate Required Deposit and Investment, as fixed on the day of the pro rata settlement charge that was the subject of the Settlement Charge Notice, plus 100% of the amount thereof, which is substantively the same limitation as provided for pro rata charges in current Section 8 of Rule 4.61

Pursuant to proposed Section 8(b), if a Participant, within five (5) Business Days after the issuance of a first Loss Allocation Notice for any round pursuant to proposed Section 5 of Rule 4 gives notice to DTC of its election to terminate its business with DTC, the Participant would remain liable for (i) the loss allocation that was the subject of such notice and (ii) all other loss allocations made by DTC with respect to the same Event Period. Subject to proposed Section 8(c), the obligation of a Participant which elects to terminate its business with DTC would be limited to the amount of its Aggregate Required Deposit and Investment, as fixed on the first day of the Event Period, plus 100% of the amount thereof, which is substantively the same limitation as provided for pro rata charges in current Section 8 of Rule 4.62

Proposed Section 8(c) would provide that under no circumstances would the aggregate obligation of a Participant under proposed Section 8(a) and proposed Section 8(b) exceed the amount of its Aggregate Required Deposit and Investment, as fixed on the earlier of the (i) day of the pro rata settlement charge that was the subject of the Settlement Charge Notice giving rise to a Termination Notice, and (ii) first day of the Event Period that was the subject of the first Loss Allocation Notice in a round giving rise to a Termination Notice, plus 100% of the amount thereof. The purpose of proposed Section 8(c) is to address a situation where a Participant could otherwise be subject to both a Settlement Charge Cap and Loss

Allocation Cap.

Proposed Section 8(d) would retain the last paragraph in current Section 8 of Rule 4, replacing "pro rata charge" with "pro rata settlement charge" and" loss allocation." 63 Proposed Section 8(d) would provide that if the amount of the Actual Participants Fund Deposit of a Participant is insufficient to satisfy a pro rata settlement charge pursuant to proposed Section 4 and proposed Section 8(a) or a loss allocation pursuant to proposed Section 5 and proposed Section 8(b), the Participant would be obligated to Deposit the amount of any such deficiency to the Participants Fund notwithstanding the fact that the Participant subsequently ceases to be a Participant.

Section 9

Pursuant to the proposed rule change, proposed Section 9 of Rule 4 would provide that the recovery and repayment provisions in current Rule 4 apply to both pro rata settlement charges and loss allocations.64 Specifically, proposed Section 9 would provide that if an amount is charged ratably pursuant to proposed Section 4 or allocated ratably pursuant to proposed Section 5 and such amount is recovered by DTC, in whole or in part, the net amount of the recovery shall be repaid ratably (on the same basis that it was originally charged or allocated) to the Persons against which the amount was originally charged or allocated by

⁶¹ See supra note 24.

⁶² See supra note 39.

⁶³ This is a ministerial change because this paragraph currently applies to current Section 4 of Rule 4, which includes charges to complete settlement and for loss allocation, as would be provided in proposed Section 4 and proposed Section 5 of Rule 4.

⁶⁴This is a ministerial change because Section 9 currently applies to current Section 4 of Rule 4, which includes charges to complete settlement and for loss allocation, as would be provided in proposed Section 4 and proposed Section 5 of Rule 4

(i) crediting the appropriate amounts to the Actual Participants Fund Deposits of Persons which are still Participants and (ii) paying the appropriate amounts in cash to Persons which are not still Participants. In addition, proposed Section 9 would clarify that no loss allocation under proposed Rule 4 would constitute a waiver of any claim DTC may have against a Participant for any losses or liabilities to which the Participant is subject under DTC Rules and Procedures, including, without limitation, any loss or liability to which it may be subject under proposed Rule 4.

DTC further proposes to add the heading "No Waiver; Recovery and Repayment" to proposed Section 9.

B. Other Proposed Clarifying, Conforming and Technical Changes to Rule 4

Section 1

Section 1(a) and Section 1(b). Section 1(a) addresses, among other things, the formula for determining the Required Participants Fund Deposits of Participants. DTC is proposing to insert the words "or wind-down" to make it clear that the formulas for determining the Required Participants Fund Deposits of Participants and the amount of the minimum Required Participants Fund Deposit would be fixed by DTC so as to assure that the aggregate amount of Required Participants Fund Deposits of Participants will be increased to provide for the costs and expenses incurred by it incidental to the wind-down of DTC, in addition to the voluntary liquidation of DTC.65 Further, DTC proposes to delete the extraneous phrase "if any." For increased clarity and readability, DTC is proposing to consolidate Section 1(b) into Section 1(a), and to relocate the sentences "The Corporation may require a Participant to Deposit an additional amount to the Participants Fund pursuant to Section 2 of Rule 9(A). Any such additional amount shall be part of the Required Participants Fund Deposit of such Participant." from Section 1(a) to a new proposed Section 1(b). In addition to the relocation, DTC would

add a defined term for such additional amount, as "Additional Participants Fund Deposit," for drafting convenience and transparency throughout proposed Rule 4. Further, DTC proposes to add the headings "Required Participants Fund Deposits" and "Additional Participants Fund Deposits" to Section 1(a) and proposed Section 1(b), respectively.

Section 1(c). For enhanced readability, DTC is proposing to add the heading "Voluntary Participants Fund Deposits" to Section 1(c) of Rule 4, and to replace the word "as" with "in the manner."

Section 1(d). For enhanced clarity, DTC is proposing to modify Section 1(d) to make it clear that any Additional Participants Fund Deposit is required to be in cash. DTC is also proposing to delete the extraneous phrase "pursuant to this Section" and to replace language regarding Section 2 of Rule 9(A) with the proposed defined term "Additional Participants Fund Deposit." Further, DTC proposes to add the heading "Cash Participants Fund" to Section 1(d) of Rule 4.

Section 1(e). For enhanced clarity, DTC is proposing to add the language "among Account Families" to clarify the scope of the allocation described in Section 1(e). In addition, DTC proposes to add the heading "Allocation of Participants Fund Deposits Among Account Families" to Section 1(e) of Rule 4.

Section 1(f). Section 1(f) addresses, among other things, the permitted use of the Participants Fund. For consistency with the balance of Section 1(f), the first paragraph would be amended to state that the Actual Participants Fund Deposits of Participants "may be used or invested" instead of stating "shall be applied." Section 1(f) provides, in part, that the Participants Fund is limited to the satisfaction of losses or liabilities of DTC incident to the business of DTC. Section 1(f) currently defines "business" with respect to DTC as "the doing of all things in connection with or relating to [DTC's] performance of the services specified in the first and second paragraphs of Rule 6 or the cessation of such services." For enhanced transparency of the permitted uses of the Participants Fund, proposed Section 1(f) would be amended to explicitly state that the Actual Participants Fund Deposits of Participants may be used (i) to satisfy the obligations of Participants to DTC, as provided in proposed Section 3, (ii) to fund settlement among nondefaulting Participants, as provided in proposed Section 4 and (iii) to satisfy losses and liabilities of DTC incident to the business of DTC, as provided in

proposed Section 5. Section 1(f) would also be amended to make the definition of "business" applicable to the entirety of Rule 4, instead of just Section 1(f), as the term would appear elsewhere in the rule pursuant to the proposed rule change. In addition, DTC proposes to add the heading "Maintenance, Permitted Use and Investment of Participants Fund" to Section 1(f) of Rule 4.

Section 1(g) (consolidated into proposed Section 1(f)). Pursuant to the proposed rule change, DTC would consolidate current Section 1(g) into proposed Section 1(f), and modify language to make it clear that DTC may invest cash in the Participants Fund in accordance with the Clearing Agency Investment Policy adopted by DTC.66 Further, language would be streamlined by replacing "securities, repurchase agreements or deposits" with "financial assets," and "securities and repurchase agreements in which such cash is invested" with "its investment of such cash."

Section 1(h) (proposed Section 1(g)). As discussed above, DTC is proposing to replace "four" years with "two" years, in order to reduce the time within which DTC would be required to return the Actual Participants Fund Deposit of a former Participant. In addition, DTC is proposing to (i) add the heading "Return of Participants Fund Deposits to Participants" to proposed Section 1(g), (ii) update a cross reference, and (iii) correct two typographical errors.

Section 2

Pursuant to the proposed rule change, Section 2 of Rule 4 would be titled "Participants Investment."

Section 2(a)–2(d) (Proposed Section 2(a)). For clarity, DTC is proposing to consolidate Sections 2(b)–2(d) into proposed Section 2(a) and would add

⁶⁵ On December 18, 2017, DTC submitted a proposed rule change and advance notice to adopt the Recovery & Wind-down Plan of DTC, and amend the Rules in order to adopt Rule 32(A) (Wind-down of the Corporation) and Rule 38 (Market Disruption and Force Majeure). See Securities Exchange Act Release Nos. 82432 (January 2, 2018), 83 FR 884 (January 8, 2018) (SR—DTC—2017—021) and 82579 (January 24, 2018), 83 FR 4310 (January 30, 2018) (SR—DTC—2017—803). On June 28, 2018, DTC filed amendments to the proposed rule change and advance notice with the Commission and the Board of Governors of the Federal Reserve System, respectively, available at http://www.dtcc.com/legal/sec-rule-filings.aspx.

⁶⁶ See Securities Exchange Act Release No. 79528 (December 12, 2016), 81 FR 91232 (December 16, 2016) (SR-DTC-2016-007). The Clearing Agency Investment Policy (the "Policy") governs the management, custody, and investment of cash deposited to the Participants Fund, the proprietary liquid net assets (cash and cash equivalents) of DTC and other funds held by DTC. The Policy sets forth guiding principles for the investment of those funds, which include adherence to a conservative investment philosophy that places the highest priority on maximizing liquidity and avoiding risk, as well as mandating the segregation and separation of funds. The Policy also addresses the process for evaluating credit ratings of counterparties and identifies permitted investments within specified parameters. In general, assets are required to be held by regulated and creditworthy financial institution counterparties and invested in financial instruments that, with respect to the Participants Fund, may include deposits with banks, including the Federal Reserve Bank of New York, collateralized reverse-repurchase agreements, direct obligations of the U.S. government and moneymarket mutual funds

the heading "Required Preferred Stock Investments" to proposed Section 2(a). In addition, DTC proposes to modify certain language to update references and cross-references to specific subsections to reflect the proposed changes to the numbering of the subsections in proposed Section 2 of Rule 4.

Section 2(e) (Proposed Section 2(b)). For enhanced clarity, DTC is proposing to add the language "among Account Families" to clarify the scope of the allocation described in proposed Section 2(b). In addition, DTC proposes to add the heading "Allocation of Preferred Stock Investments Among Account Families" to proposed Section 2(b) of Rule 4.

Section 2(f) (Proposed Section 2(c)). DTC is proposing to add language to clarify that when any Pledge of a Preferred Stock Security Interest pursuant to proposed Section 2(c) of Rule 4 is made by appropriate entries on the books of DTC, the Rules, in addition to such entries, shall be deemed to be a security agreement for purposes of the New York Uniform Commercial Code. In addition, DTC proposes to update a cross-reference to proposed Section 2(c). In addition, DTC proposes to add the heading "Security Interest in Preferred

Stock Investments of Participants" to

proposed Section 2(c).

Sections 2(g)–2(i) (Proposed Sections 2(d)–2(f)). DTC proposes to add the headings "Dividends on Preferred Stock Investments of Participants," "Sale of Preferred Stock Investments of Participants," and "Permitted Transfers of Preferred Stock Investments of Participants" to proposed Sections 2(d), 2(e), and 2(f), respectively. Proposed Sections 2(e) and 2(f) would be modified to update cross-references to certain subsections. In addition, proposed Section 2(f) would be modified to renumber paragraphs and internal lists for consistency with the numbering schemes in Rule 4.

Section 7. For clarity, DTC is proposing to amend Section 7 of Rule 4 to (i) replace language referencing Additional Participants Fund Deposits with the proposed defined term, (ii) update cross-references to reflect proposed renumbering, and (iii) add the headings "Increased Participants Fund Deposits and Preferred Stock Investments," "Required Participants Fund Deposits," and "Required Preferred Stock Investments" to proposed Sections 7, 7(a) and 7(b) of Rule 4, respectively.

C. Proposed Changes to Rule 1

DTC is proposing to amend Rule 1 (Definitions; Governing Law) to add

cross-references to proposed terms that would be defined in Rule 4, and to delete one defined term. The defined terms to be added are: "Additional Participants Fund Deposit," "Corporate Contribution," "CTA Participant," "Declared Non-Default Loss Event," "Default Loss Event," "Event Period," "Loss Allocation Cap," "Loss Allocation Notice," "Loss Allocation Termination Notification Period," "Participant Default," "Participant Termination Date," "Settlement Charge Cap," "Settlement Charge Notice," "Settlement Charge Termination Notification Period," "Termination Notice," "Voluntary Retirement," Voluntary Retirement Date," and "Voluntary Retirement Notice". The term "Section 8 Pro Rata Charge" would be deleted from Rule 1, because it would be deleted from proposed Rule 4 as no longer necessary.

D. Proposed Changes to Rule 2

Section 1. The proposed rule change would modify Section 1 of Rule 2 by adding "subject to Section 6 of Rule 4" to the end of the following provision: "A Participant may terminate its business with the Corporation by notifying the Corporation as provided in Sections 7 or 8 of Rule 4 or, if for a reason other than those specified in said Sections 7 and 8, by notifying the Corporation thereof; the Participant shall, upon receipt of such notice by the Corporation, cease to be a Participant." DTC is proposing to add this language in order to clarify that the termination would be subject to the requirements in proposed Section 6 of Rule 4.

Participant Outreach

Beginning in August 2017, DTC has conducted outreach to Participants in order to provide them with advance notice of the proposed changes. As of the date of this filing, no written comments relating to the proposed changes have been received in response to this outreach. The Commission will be notified of any written comments received.

Implementation Timeframe

Pending Commission approval, DTC expects to implement this proposal within two (2) Business Days after approval. Participants would be advised of the implementation date of this proposal through issuance of a DTC Important Notice.

2. Statutory Basis

DTC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. Specifically, DTC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) of the Act ⁶⁷ and Rules 17Ad–22(e)(7)(i), 17Ad–22(e)(13) and (e)(23)(i), ⁶⁸ each as promulgated under the Act, for the reasons described below.

Section 17A(b)(3)(F) of the Act requires that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible.⁶⁹ The proposed rule changes to (1) require a Corporate Contribution to a loss, (2) introduce an Event Period, and (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Participant termination process in connection with the loss allocation process, taken together, are intended to enhance the overall resiliency of DTC's loss allocation process

By replacing the discretionary application of DTC retained earnings to losses and liabilities with a mandatory and defined amount of the Corporate Contribution, the proposed rule change is designed to provide enhanced transparency and accessibility to Participants as to how much DTC would contribute in the event of a loss or liability. The proposed rule change also clarifies that the proposed Corporate Contribution would apply to both Default Loss Events and Declared Non-Default Loss Events. The proposed rule change would provide greater transparency as to the proposed replenishment period for the Corporate Contribution, which would allow Participants to better assess the adequacy of DTC's loss allocation process. Taken together, the proposed rule changes with respect to the Corporate Contribution would enhance the overall resiliency of DTC's loss allocation process by specifying the calculation and application of DTC's Corporate Contribution, including the proposed replenishment period, and would allow Participants to better assess the adequacy of DTC's loss allocation process.

By introducing the concept of an Event Period, DTC would be able to group Default Loss Events and Declared Non-Default Loss Events occurring within a period of ten (10) Business

^{67 15} U.S.C. 78q-1(b)(3)(F).

 $^{^{68}\,17}$ CFR 240.17Ad–22(e)(7)(i), (e)(13) and (e)(23)(i).

^{69 15} U.S.C. 78q-1(b)(3)(F).

Days for purposes of allocating losses to Participants. DTC believes that the Event Period would provide a defined structure for the loss allocation process to encompass potential sequential Default Loss Events or Declared Non-Default Loss Events that may or may not be closely linked to an initial event and/ or a market dislocation episode. Having this structure would enhance the overall resiliency of DTC's loss allocation process because the proposed rule would expressly address losses that may arise from multiple Default Loss Events and/or Declared Non-Default Loss Events that arise in quick succession. Moreover, the proposed Event Period structure would provide certainty for Participants concerning their maximum exposure to mutualized loss allocation with respect to such events.

By introducing the concept of "rounds" (and accompanying Loss Allocation Notices) and applying this concept to the timing of loss allocation payments and the Participant termination process in connection with the loss allocation process, DTC would (i) set forth a defined amount that it would allocate to Participants during each round (*i.e.*, the round cap), (ii) advise Participants of loss allocation obligation information as well as round information through the issuance of Loss Allocation Notices, and (iii) provide Participants with the option to limit their loss allocation exposure after the issuance of the first Loss Allocation Notice in each round. These proposed rule changes would enhance the overall resiliency of DTC's loss allocation process because they would expressly permit DTC to continue the loss allocation process in successive rounds until all of DTC's losses are allocated and enable DTC to identify continuing Participants for purposes of calculating subsequent loss allocation obligations in successive rounds. Moreover, the proposed rule changes would define for Participants a clear manner and process in which they could cap their loss allocation exposure to DTC.

Taken together, the foregoing proposed rule changes would establish a stronger (for all the reasons discussed above) and clearer loss allocation process for DTC, which DTC believes would allow it to take timely action to address losses. The ability to timely address losses would allow DTC to continue to meet its clearance and settlement obligations, especially in circumstances that may involve a series of substantially contemporaneous loss events. Therefore, DTC believes that these proposed rule changes would promote the prompt and accurate clearance and settlement of securities

transactions, consistent with Section 17A(b)(3)(F) of the Act.

By reducing the time within which DTC is required to return the Actual Participants Fund Deposit of a former Participant, DTC would enable firms that have exited DTC to have access to their funds sooner than under current Rule 4 while maintaining the protection of DTC and its provision of clearance and settlement services. DTC would continue to be protected under the proposed rule change, which will maintain the provision that DTC may offset the return of funds against the amount of any loss or liability of DTC arising out of or relating to the obligations of the former Participant to DTC, and would provide that DTC could retain the funds for up to two (2) years. As such, DTC would maintain a necessary level of coverage for possible claims arising in connection with the DTC activities of a former Participant. Therefore, DTC believes that this proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of

The proposed rule changes to clarify the Voluntary Retirement of a Participant would improve the clarity of the Rule and help to ensure that DTC's Voluntary Retirement process is transparent and clear to Participants. Having clear Voluntary Retirement provisions would enable Participants to better understand the Voluntary Retirement process and provide Participants with increased predictability and certainty regarding their rights and obligations with respect to such process. Enabling Participants to readily understand DTC's Voluntary Retirement process and their rights and obligations in connection thereto would help a Participant that is voluntarily terminating its business with DTC, and the membership at large, to understand the point at which a Participant may no longer a Participant of DTC, and would thereby promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act.

Rule 17Ad–22(e)(7)(i) under the Act requires, in part, that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to effectively measure, monitor, and manage the liquidity risk that arises in or is borne by DTC, including measuring, monitoring, and managing its settlement and funding flows on an ongoing and timely basis, and its use of intraday liquidity, by maintaining sufficient liquid resources to effect same-day

settlement of payment obligations with a high degree of confidence under a wide range of foreseeable stress scenarios.⁷⁰ By clarifying the remedies available to DTC with respect to a Participant Default, including the application of the Participants Fund as a liquidity resource, and by clarifying and providing the related processes, the proposed rule change is designed so that DTC may manage its settlement and funding flows on a timely basis and apply the Participants Fund as a liquid resource in order to effect same day settlement of payment obligations with a high degree of confidence. Therefore, DTC believes that the proposed rule changes with respect to the application of the Actual Participants Fund Deposits of non-defaulting Participants to complete settlement are consistent with Rule 17Ad-22(e)(7)(i) under the Act.

Rule 17Ad-22(e)(13) under the Act requires, in part, that DTC establish, implement, maintain and enforce written policies and procedures reasonably designed to ensure DTC has the authority and operational capacity to take timely action to contain losses and liquidity demands and continue to meet its obligations.71 The proposed rule changes to (1) require a defined Corporate Contribution to a loss, (2) introduce an Event Period, (3) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Participant termination process in connection with the loss allocation process, taken together, are designed to enhance the resiliency of DTC's loss allocation process. Having a resilient loss allocation process would help ensure that DTC can effectively and timely address losses relating to or arising out of Default Loss Events and/ or Declared Non-Default Loss Events, which in turn would help DTC contain losses and continue to conduct its clearance and settlement business. In addition, by providing clarity as to the application of the Participants Fund to fund settlement in the event of a Participant Default, the proposed rule change is designed to clarify that DTC is authorized to use the Participants Fund to fund settlement. Therefore, DTC believes that the proposed rule changes to enhance the resiliency of DTC's loss allocation process, and to provide clarity as to the application of the Participants Fund to fund settlement, are consistent with Rule 17Ad-22(e)(13) under the Act.

⁷⁰ 17 CFR 240.17Ad-22(e)(7)(i).

⁷¹ Id. at 240.17Ad-22(e)(13).

Rule 17Ad-22(e)(23)(i) under the Act requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to publicly disclose all relevant rules and material procedures, including key aspects of DTC's default rules and procedures.⁷² The proposed rule changes to (i) separate the provisions for the use of the Participants Fund for settlement and for loss allocation, (ii) make clarifying changes to the provisions regarding the application of the Participants Fund to complete settlement and for the allocation of losses, (iii) further align the loss allocation rules of the DTCC Clearing Agencies, (iv) improve the overall transparency and accessibility of the provisions in the Rules governing loss allocation, and (v) make technical and conforming changes, would not only ensure that DTC's loss allocation rules are, to the extent practicable and appropriate, consistent with the loss allocation rules of the other DTCC Clearing Agencies, but also would help to ensure that DTC's loss allocation rules are transparent and clear to Participants. Aligning the loss allocation rules of the DTCC Clearing Agencies would provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and clear loss allocation rules would enable Participants to better understand the key aspects of DTC's Rules and Procedures relating to Participant Default, as well as non-default events, and provide Participants with increased predictability and certainty regarding their exposures and obligations. As such, DTC believes that the proposed rule changes with respect to pro rata settlement charges, and to align the loss allocation rules across the DTCC Clearing Agencies and to improve the overall transparency and accessibility of DTC's loss allocation rules are consistent with Rule 17Ad-22(e)(23)(i) under the Act.

The proposed rule changes to clarify the Voluntary Retirement of a Participant would improve the clarity of the Rules and help to ensure that DTC's Voluntary Retirement process is transparent and clear to Participants. Having clear Voluntary Retirement provisions would enable Participants to better understand the Voluntary Retirement process and provide Participants with increased predictability and certainty regarding their rights and obligations with respect to such process. As such, DTC believes

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe that the proposed rule changes to clarify the remedies available to DTC with respect to a Participant Default, including the application of the Participants Fund as a liquidity resource, and to clarify and provide the related processes, would impact competition.⁷³ The proposed rule changes retain the existing core concepts of the pro rata use of the Participants Fund deposits of nondefaulting Participants to complete settlement when a Participant fails to settle, and does not materially change their rights to elect to terminate their business with DTC and limit their exposure to settlement charges. Based on the foregoing, DTC believes that the proposed rule changes relating to pro rata settlement charges would not have any impact on competition.

DTC believes that the proposed rule change to replace the discretionary application of DTC retained earnings to losses and liabilities with a mandatory and defined Corporate Contribution would impact competition, but would not impose a burden on competition.74 By requiring a defined corporate contribution to losses and liabilities that are incurred by DTC before the allocation of losses to Participants, the proposed rule change would relieve Participants of a defined amount of potential obligations, which would allow them to apply those resources elsewhere. Based on the foregoing, DTC believes that the proposed rule changes relating to the Corporate Contribution would not impose a burden on competition, but may promote competition.

DTC does not believe that the proposed rule changes to enhance the resiliency of DTC's loss allocation process would impact competition.⁷⁵ As described above, the proposed rule changes to (1) introduce an Event Period, and (2) introduce the concept of "rounds" (and accompanying Loss Allocation Notices) and apply this concept to the timing of loss allocation payments and the Participant termination process in connection with the loss allocation process, taken together, are intended to enhance the overall resiliency of DTC's loss allocation process, and would apply

equally to all Participants. Moreover, the proposed changes with respect to loss allocation retain the core concept of the allocation of losses and liabilities among Participants proportionally to the amount of risk that their activities present to DTC as measured by their Required Participants Fund Deposits.⁷⁶ Since there would not be a change to the mutualized obligations with respect to a loss arising from a Default Loss Event or Declared Non-Default Loss Event, the proposed rule changes with respect to loss allocation would not substantively affect the rights and obligations of Participants.

DTC believes that the proposed rule change to reduce the time after a Participant ceases to be a Participant within which DTC would be required to return the amount of the Actual Participants Fund Deposit of the former Participant may have an impact on competition, but would not impose a burden on competition.⁷⁷ This proposed rule change is intended to enable firms who have exited DTC to have use of their funds sooner, while at the same time retaining the existing requirements around the return. The reduction of the applicable timeframe from four (4) years to two (2) years would improve systemic efficiency by releasing the resources of the former Participant sooner, allowing them to allocate those resources where needed. Based on the foregoing, DTC believes the proposed rule change to reduce the time within which DTC is required to return the Actual Participants Fund Deposit of a former Participant would not impose a burden on competition, but may promote competition.

DTC also does not believe that the proposed rule changes to (i) further align the loss allocation rules of the DTCC Clearing Agencies, (ii) increase the transparency and accessibility of provisions in the Rules governing loss allocation, and (iii) make technical and conforming changes, would impact competition.⁷⁸ These changes would apply equally to all Participants. Further alignment of the loss allocation rules of the DTCC Clearing Agencies are intended to increase the consistency of the Rules with the rules of other DTCC Clearing Agencies in order to provide consistent treatment, to the extent practicable and appropriate, especially for firms that are participants of two or more DTCC Clearing Agencies. Having transparent and accessible provisions in the Rules governing loss allocation are intended to improve the readability and

that the proposed rule changes with respect to Voluntary Retirement are also consistent with Rule 17Ad–22(e)(23)(i) under the Act.

^{73 15} U.S.C. 78q-1(b)(3)(I).

⁷⁴ Id.

⁷⁵ Id.

⁷⁶ Supra note 14.

^{77 15} U.S.C. 78q-1(b)(3)(I).

⁷⁸ Id.

⁷² Id. at 240.17Ad-22(e)(23)(i).

clarity of the Rules regarding the loss allocation process. Clarifying DTC's Voluntary Retirement provisions would improve the clarity of the Rules and help ensure that DTC's Voluntary Retirement process is transparent and clear to all Participants. Making technical and conforming changes to ensure the Rules remain clear and accurate would facilitate Participants' understanding of the Rules and their obligations thereunder. As such, DTC believes that these proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to this proposed rule change have not been solicited or received. DTC will notify the Commission of any written comments received by DTC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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–DTC–2017–022 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-DTC-2017-022. 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 website (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 website 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 DTC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-DTC-2017-022 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 79

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15364 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83628; File No. SR-DTC-2017-021]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing of Amendment No. 1 to a Proposed Rule Change To Adopt a Recovery & Wind-Down Plan and Related Rules

July 13, 2018.

On December 18, 2017, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") and Rule 19b–4 thereunder, proposed rule change SR–DTC–2017–021 ("Proposed Rule Change") to adopt a recovery and wind-down plan and related rules. 1 The

Proposed Rule Change was published for comment in the Federal Register on January 8, 2018.² On February 8, 2018, the Commission designated a longer period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change.³ On March 20, 2018, the Commission instituted proceedings to determine whether to approve or disapprove the Proposed Rule Change.⁴ On June 25, 2018, the Commission designated a longer period for Commission action on the proceedings to determine whether to approve or disapprove the Proposed Rule Change.⁵ On June 28, 2018, DTC filed Amendment No. 1 to the Proposed Rule Change to amend and replace in its entirety the Proposed Rule Change as originally submitted on December 18, 2017.6 As of the date of this release, the

Commission required additional information for consideration of the Advance Notice, pursuant to Section 806(e)(1)(D) of the Clearing Supervision Act, which provided the Commission with an additional 60-days in the review period beginning on the date that the information requested is received by the Commission. (12 U.S.C. 5465(e)(1)(D).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Commission's Request for Additional Information," available at http:// www.sec.gov/rules/sro/dtc-an.shtml. On June 28, 2018, DTC filed Amendment No. 1 to the Advance Notice. To promote the public availability and transparency of its post-notice amendment, DTC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Advance Notice has been posted on the Commission's website at https://www.sec.gov/rules/ sro/dtc-an.htm and thus been publicly available since June 29, 2018. On July 6, 2018, the Commission received the information requested, which added an additional 60-days to the review period pursuant to Sections 806(e)(1)(E) and (G) of the Clearing Supervision Act. (12 U.S.C 5465(e)(1)(E) and (G).) See Memorandum from the Office of Clearance and Settlement Supervision, Division of Trading and Markets, titled "Response to the Commission's Request for Additional Information," available at http://www.sec.gov/ rules/sro/dtc-an.shtml. The proposal, as set forth in both the Advance Notice and the Proposed Rule Change, shall not take effect until all required regulatory actions are completed.

² Securities Exchange Act Release No. 82432 (January 2, 2018), 83 FR 884 (January 8, 2018) (SR–DTC–2017–021).

³ Securities Exchange Act Release No. 82669 (February 8, 2018), 83 FR 6653 (February 14, 2018) (SR-DTC-2017-021; SR-FICC-2017-021; SR-NSCC-2017-017).

⁴ Securities Exchange Act Release No. 82912 (March 20, 2018), 83 FR 12999 (March 26, 2018) (SR-DTC-2017-021).

⁵ Securities Exchange Act Release No. 83509 (June 25, 2018), 83 FR 30785 (June 29, 2018) (SR–DTC–2017–021; SR–FICC–2017–021; SR–NSCC–2017–017).

⁶ To promote the public availability and transparency of its post-notice amendment, DTC submitted a copy of Amendment No. 1 through the Commission's electronic public comment letter mechanism. Accordingly, Amendment No. 1 to the Proposed Rule Change has been posted on the

Continued

⁷⁹ 17 CFR 200.30–3(a)(12).

¹¹⁵ U.S.C. 78s(b)(1) and 17 CFR 240.19b-4, respectively. On December 18, 2017, DTC filed the Proposed Rule Change as advance notice SR-DTC-2017-803 ("Advance Notice") with the Commission pursuant to Section 806(e)(1) of Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 ("Clearing Supervision Act") and Rule 19b-4(n)(1)(i) of the Act. (12 U.S.C. 5465(e)(1) and 17 CFR 240.19b 4(n)(1)(i), respectively.) On January 30, 2018, the Commission published in the Federal Register notice of filing of the Advance Notice. The notice also extended the review period for the Advance Notice pursuant to Section 806(e)(1)(H) of the Clearing Supervision Act. (12 U.S.C. 5465(e)(1)(H).) See Securities Exchange Act Release No. 82579 (January 24, 2018), 83 FR 4310 (January 30, 2018) (SR-DTC-2017-803). On April 10, 2018, the

Commission has not received any comments on the Proposed Rule

The Proposed Rule Change, as amended by Amendment No. 1, is described in Items I and II below, which Items have been prepared by DTC. The Commission is publishing this notice to solicit comments on the Proposed Rule Change, as amended by Amendment No. 1, from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The Proposed Rule Change of DTC proposes to (1) adopt the Recovery & Wind-down Plan of DTC ("R&W Plan" or "Plan"); and (2) amend the Rules, By-Laws and Organization Certificate of DTC ("Rules") ⁷ in order to adopt Rule 32(A) (Wind-down of the Corporation) and Rule 38 (Market Disruption and Force Majeure) (each proposed Rule 32(A) and proposed Rule 38, a "Proposed Rule" and, collectively, the "Proposed Rules").

The R&W Plan would be maintained by DTC in compliance with Rule 17Ad-22(e)(3)(ii) under the Act by providing plans for the recovery and orderly winddown of DTC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described below.8 The Proposed Rules are designed to (1) facilitate the implementation of the R&W Plan when necessary and, in particular, allow DTC to effectuate its strategy for winding down and transferring its business; (2) provide Participants with transparency around critical provisions of the R&W Plan that relate to their rights, responsibilities and obligations; and (3) provide DTC with the legal basis to implement those provisions of the R&W Plan when necessary, as described below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency 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 III below. The clearing agency has prepared

Commission's website at https://www.sec.gov/rules/ sro/dtc.htm and thus been publicly available since June 29, 2018. summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Description of Amendment No. 1

This filing constitutes Amendment No. 1 ("Amendment") to the Proposed Rule Change (also referred to below as the "Original Filing") previously filed by DTC.9 DTC is amending the proposed R&W Plan and the Original Filing in order to clarify certain matters and make minor technical and conforming changes to the R&W Plan, as described below and as marked on Exhibit 4 hereto. To the extent such changes to the Plan require changes to the Original Filing, the information provided under "Description of Proposed Changes" in the Original Filing has been amended and is restated in its entirety below. Other sections of the Original Filing are unchanged and are restated in their entity for convenience.

First, this Amendment would clarify the use in the Plan of the term "Participant Default Losses." This Amendment would also clarify the actions and tools available in the third phase of the Crisis Continuum, which is referred to as the "Participant Default phase." This Amendment would also make conforming changes as necessary to reflect the use of these terms.

Second, this Amendment would clarify that actions and tools described in the Plan that are available in one phase of the Crisis Continuum may be used in subsequent phases of the Crisis Continuum, when appropriate to address the applicable situation. This Amendment would also clarify that allocation of losses resulting from a Participant Default would be applied when provide for in, and in accordance with, Rule 4.

Third, this Amendment would clarify that the Recovery Corridor (as defined therein) is not a "sub-phase" of the recovery phase. Rather, the Recovery Corridor is a period of time that would occur toward the end of the Participant Default phase, when indicators are that DTC may transition into the recovery phase. Thus, the Recovery Corridor precedes the recovery phase.

Fourth, this Amendment would make revisions to address the allocation of losses resulting from a Participant Default in order to more closely conform such statements to the changes proposed by the Loss Allocation Filing, as defined below.

Fifth, this Amendment would clarify the notifications that DTC would be required to make under the Proposed Rule 38 (Market Disruption and Force Majeure).

Finally, this Amendment would make minor, technical and conforming revisions to correct typographical errors and to simplify descriptions. For example, such revisions would use lower case for terms that are not defined therein, and would use upper case for terms that are defined. The Amendment would also simplify certain descriptions by removing extraneous words and statements that are repetitive. These minor, technical revisions would not alter the substance of the proposal.

Description of Proposed Changes

DTC is proposing to adopt the R&W Plan to be used by the Board and management in the event DTC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would identify (i) the recovery tools available to DTC to address the risks of (a) uncovered losses or liquidity shortfalls resulting from the default of one or more of its Participants, and (b) losses arising from non-default events, such as damage to its physical assets, a cyber-attack, or custody and investment losses, and (ii) the strategy for implementation of such tools. The R&W Plan would also establish the strategy and framework for the orderly wind-down of DTC and the transfer of its business in the remote event the implementation of the available recovery tools does not successfully return DTC to financial viability.

As discussed in greater detail below, the R&W Plan would provide, among other matters, (i) an overview of the business of DTC and its parent, The **Depository Trust & Clearing Corporation** ("DTCC"); (ii) an analysis of DTC's intercompany arrangements and critical links to other financial market infrastructures ("FMIs"); (iii) a description of DTC's services, and the criteria used to determine which services are considered critical; (iv) a description of the DTC and DTCC governance structure; (v) a description of the governance around the overall recovery and wind-down program; (vi) a discussion of tools available to DTC to mitigate credit/market and liquidity risks, including recovery indicators and triggers, and the governance around management of a stress event along a "Crisis Continuum" timeline; (vii) a

⁷ Capitalized terms used herein and not otherwise defined herein are defined in the Rules, available at www.dtcc.com/~/media/Files/Downloads/legal/rules/DTC rules.pdf.

^{8 17} CFR 240.17Ad-22(e)(3)(ii).

⁹ See Securities Exchange Act Release No. 82579 (January 24, 2018), 83 FR 4310 (January 30, 2018) (SR–DTC–2017–803).

discussion of potential non-default losses and the resources available to DTC to address such losses, including recovery triggers and tools to mitigate such losses; (viii) an analysis of the recovery tools' characteristics, including how they are comprehensive, effective, and transparent, how the tools provide appropriate incentives to Participants to, among other things, control and monitor the risks they may present to DTC, and how DTC seeks to minimize the negative consequences of executing its recovery tools; and (ix) the framework and approach for the orderly wind-down and transfer of DTC's business, including an estimate of the time and costs to effect a recovery or orderly wind-down of DTC.

The R&W Plan would be structured as a roadmap, and would identify and describe the tools that DTC may use to effect a recovery from the events and scenarios described therein. Certain recovery tools that would be identified in the R&W Plan are based in the Rules (including the Proposed Rules) and, as such, descriptions of those tools would include descriptions of, and reference to, the applicable Rules and any related internal policies and procedures. Other recovery tools that would be identified in the R&W Plan are based in contractual arrangements to which DTC is a party, including, for example, existing committed or pre-arranged liquidity arrangements. Further, the R&W Plan would state that DTC may develop further supporting internal guidelines and materials that may provide operationally for matters described in the Plan, and that such documents would be supplemental and subordinate to the Plan.

Key factors considered in developing the R&W Plan and the types of tools available to DTC were its governance structure and the nature of the markets within which DTC operates. As a result of these considerations, many of the tools available to DTC that would be described in the R&W Plan are DTC's existing, business-as-usual risk management and default management tools, which would continue to be applied in scenarios of increasing stress. In addition to these existing, businessas-usual tools, the R&W Plan would describe DTC's other principal recovery tools, which include, for example, (i) identifying, monitoring and managing general business risk and holding sufficient liquid net assets funded by equity ("LNA") to cover potential general business losses pursuant to the Clearing Agency Policy on Capital

Requirements ("Capital Policy"), ¹⁰ (ii) maintaining the Clearing Agency Capital Replenishment Plan ("Replenishment Plan") as a viable plan for the replenishment of capital should DTC's equity fall close to or below the amount being held pursuant to the Capital Policy, ¹¹ and (iii) the process for the allocation of losses among Participants as provided in Rule 4. ¹² The R&W Plan would provide governance around the selection and implementation of the recovery tool or tools most relevant to mitigate a stress scenario and any applicable loss or liquidity shortfall.

The development of the R&W Plan is facilitated by the Office of Recovery & Resolution Planning ("R&R Team") of DTCC.¹³ The R&R Team reports to the **DTCC Management Committee** ("Management Committee") and is responsible for maintaining the R&W Plan and for the development and ongoing maintenance of the overall recovery and wind-down planning process. The Board, or such committees as may be delegated authority by the Board from time to time pursuant to its charter, would review and approve the R&W Plan biennially, and would also review and approve any changes that are proposed to the R&W Plan outside of the biennial review.

As discussed in greater detail below, the Proposed Rules would define the procedures that may be employed in the event of a DTC wind-down, and would provide for DTC's authority to take certain actions on the occurrence of a "Market Disruption Event," as defined therein. Significantly, the Proposed Rules would provide Participants with transparency and certainty with respect

to these matters. The Proposed Rules would facilitate the implementation of the R&W Plan, particularly DTC's strategy for winding down and transferring its business, and would provide DTC with the legal basis to implement those aspects of the R&W Plan.

DTC R&W Plan

The R&W Plan is intended to be used by the Board and DTC's management in the event DTC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be structured to provide a roadmap, define the strategy, and identify the tools available to DTC to either (i) recover, in the event it experiences losses that exceed its prefunded resources (such strategies and tools referred to herein as the "Recovery Plan") or (ii) wind-down its business in a manner designed to permit the continuation of its critical services in the event that such recovery efforts are not successful (such strategies and tools referred to herein as the "Wind-down Plan"). The description of the R&W Plan below is intended to highlight the purpose and expected effects of the material aspects of the R&W Plan, and to provide Participants with appropriate transparency into these features.

Business Overview, Critical Services, and Governance

The introduction to the R&W Plan would identify the document's purpose and its regulatory background, and would outline a summary of the Plan. The stated purpose of the R&W Plan is that it is to be used by the Board and DTC management in the event DTC encounters scenarios that could potentially prevent it from being able to provide its critical services as a going concern. The R&W Plan would be maintained by DTC in compliance with Rule 17Ad–22(e)(3)(ii) under the Act ¹⁴ by providing plans for the recovery and orderly wind-down of DTC.

The R&W Plan would describe DTCC's business profile, provide a summary of DTC's services, and identify the intercompany arrangements and critical links between DTC and other FMIs. This overview section would provide a context for the R&W Plan by describing DTC's business, organizational structure and critical links to other entities. By providing this context, this section would facilitate the analysis of the potential impact of utilizing the recovery tools set forth in later sections of the Recovery Plan, and

¹⁰ See Securities Exchange Act Release No. 81105 (July 7, 2017), 82 FR 32399 (July 13, 2017) (SR– DTC–2017–003; SR–FICC–2017–007; SR–NSCC– 2017–004).

¹¹ See id

 $^{^{12}\,}See$ Rule 4 (Participants Fund and Participants Investment), supra note 7. DTC is proposing changes to Rule 4 regarding allocation of losses in a separate filing submitted simultaneously with the Original Filing. See Securities Exchange Act Release Nos. 82432 (January 2, 2018), 83 FR 884 (January 8, 2018) (SR-DTC-2017-021) and 82579 (January 24, 2018), 83 FR 4310 (January 30, 2018) (SR-DTC-2017-803) (collectively referred to herein as the "Loss Allocation Filing"). DTC has submitted an amendment to the Loss Allocation Filing. A copy of the amendment to the Loss Allocation Filing is available at http://www.dtcc.com/legal/sec-rulefilings.aspx. DTC expects the Commission to review both proposals, as amended, together, and, as such, the proposal described in this filing anticipates the approval and implementation of those proposed changes to the Rules.

¹³ DTCC operates on a shared services model with respect to DTC and its other subsidiaries. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements under which it is generally DTCC that provides a relevant service to a subsidiary, including DTC.

¹⁴ 17 CFR 240.17Ad-22(e)(3)(ii).

the analysis of the factors that would be addressed in implementing the Winddown Plan.

DTCC is a user-owned and user-governed holding company and is the parent company of DTC and its affiliates, National Securities Clearing Corporation ("NSCC") and Fixed Income Clearing Corporation ("FICC," and, together with NSCC and DTC, the "Clearing Agencies"). The Plan would describe how corporate support services are provided to DTC from DTCC and DTCC's other subsidiaries through intercompany agreements under a shared services model.

The Plan would provide a description of established links between DTC and other FMIs, both domestic and foreign, including central securities depositories ("CSDs") and central counterparties ("CCPs"), as well as the twelve U.S. Federal Reserve Banks. In general, these links are either "inbound" or "issuer" links, in which the other FMI is a Participant and/or a Pledgee and maintains one or more accounts at DTC, or "outbound" or "investor" links in which DTC maintains one or more accounts at another FMI. Key FMIs with which DTC maintains critical links include CDS Clearing and Depository Services Inc. ("CDS"), the Canadian CSD, with participant links in both directions; Euroclear Bank SA/NV ("EB") for cross-border collateral management services; and The Options Clearing Corporation ("OCC") and the Federal Reserve Bank of New York ("FRBNY"), each of which is both a Participant and a Pledgee. The critical link for the U.S. marketplace is the relationship between DTC and NSCC, through which continuous net settlement ("CNS") transactions are completed by settlement at DTC, and DTC acts as settlement agent for NSCC for end-of-day funds settlement.¹⁵ This section of the Plan, identifying and briefly describing DTC's established links, would provide a mapping of critical connections and dependencies that may need to be relied on or otherwise addressed in connection with the implementation of either the Recovery Plan or the Wind-down Plan.

The Plan would define the criteria for classifying certain of DTC's services as "critical," and would identify those critical services and the rationale for their classification. This section would provide an analysis of the potential systemic impact from a service disruption, and is important for evaluating how the recovery tools and

the wind-down strategy would facilitate and provide for the continuation of DTC's critical services to the markets it serves. The criteria that would be used to identify a DTC service or function as critical would include consideration as to (1) whether there is a lack of alternative providers or products; (2) whether failure of the service could impact DTC's ability to perform its book-entry and settlement services; (3) whether failure of the service could impact DTC's ability to perform its payment system functions; and (4) whether the service is interconnected with other participants and processes within the U.S. financial system, for example, with other FMIs, settlement banks and broker-dealers. The Plan would then list each of those services, functions or activities that DTC has identified as "critical" based on the applicability of these four criteria. Such critical services would include, for example, MMIs and Commercial Paper Processing, 16 Mandatory and Voluntary Corporate Actions, 17 Cash and Stock Distributions, 18 and End of Day Net Money Settlement.¹⁹ The R&W Plan would also include a non-exhaustive list of DTC services that are not deemed critical.

The evaluation of which services provided by DTC are deemed critical is important for purposes of determining how the R&W Plan would facilitate the continuity of those services. As discussed further below, while DTC's Wind-down Plan would provide for the transfer of all critical services to a transferee in the event DTC's winddown is implemented, it would anticipate that any non-critical services that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership, would also be transferred.

The Plan would describe the governance structure of both DTCC and DTC. This section of the Plan would identify the ownership and governance model of these entities at both the Board of Directors and management levels. The Plan would state that the stages of escalation required to manage recovery under the Recovery Plan or to invoke

DTC's wind-down under the Winddown Plan would range from relevant business line managers up to the Board through DTC's governance structure. The Plan would then identify the parties responsible for certain activities under both the Recovery Plan and the Winddown Plan, and would describe their respective roles. The Plan would identify the Risk Committee of the Board ("Board Risk Committee") as being responsible for oversight of risk management activities at DTC, which include focusing on both oversight of risk management systems and processes designed to identify and manage various risks faced by DTC, and, due to DTC's critical role in the markets in which it operates, oversight of DTC's efforts to mitigate systemic risks that could impact those markets and the broader financial system.²⁰ The Plan would identify the DTCC Management Risk Committee ("Management Risk Committee") as primarily responsible for general, day-to-day risk management through delegated authority from the Board Risk Committee. The Plan would state that the Management Risk Committee has delegated specific dayto-day risk management, including management of risks addressed through margining systems and related activities, to the DTCC Group Chief Risk Office ("GCRO"), which works with staff within the DTCC Financial Risk Management group. Finally, the Plan would describe the role of the Management Committee, which provides overall direction for all aspects of DTC's business, technology, and operations and the functional areas that support these activities.

The Plan would describe the governance of recovery efforts in response to both default losses and nondefault losses under the Recovery Plan, identifying the groups responsible for those recovery efforts. Specifically, the Plan would state that the Management Risk Committee provides oversight of actions relating to the default of a Participant, which would be reported and escalated to it through the GCRO, and the Management Committee provides oversight of actions relating to non-default events that could result in a loss, which would be reported and escalated to it from the DTCC Chief Financial Officer ("CFO") and the DTCC Treasury group that reports to the CFO. and from other relevant subject matter experts based on the nature and circumstances of the non-default

¹⁵ DTC has other links in addition to those mentioned above. The current list of linked CSDs is available on the DTCC website.

 $^{^{16}\,}See$ Rule 9(C) (Transactions in MMI Securities), supra note 7.

¹⁷ See DTC Reorganizations Service Guide, available at www.dtcc.com/~/media/Files/ Downloads/legal/service-guides/ Reorganizations.pdf.

¹⁸ See DTC Distributions Service Guide, available at http://www.dtcc.com/~/media/Files/Downloads/ legal/service-guides/Service%20Guide %20Distributions.pdf.

¹⁹ See DTC Settlement Service Guide, available at www.dtcc.com/~/media/Files/Downloads/legal/service-guides/Settlement.pdf.

²⁰ The charter of the Board Risk Committee is available at http://www.dtcc.com/~/media/Files/Downloads/legal/policy-and-compliance/DTCC-BOD-Risk-Committee-Charter.pdf.

event.²¹ More generally, the Plan would state that the type of loss and the nature and circumstances of the events that lead to the loss would dictate the components of governance to address that loss, including the escalation path to authorize those actions. As described further below, both the Recovery Plan and the Wind-down Plan would describe the governance of escalations, decisions, and actions under each of those plans.

Finally, the Plan would describe the role of the R&R Team in managing the overall recovery and wind-down program and plans for each of the Clearing Agencies.

DTC Recovery Plan

The Recovery Plan is intended to be a roadmap of those actions that DTC may employ to monitor and, as needed, stabilize its financial condition. As each event that could lead to a financial loss could be unique in its circumstances, the Recovery Plan would not be prescriptive and would permit DTC to maintain flexibility in its use of identified tools and in the sequence in which such tools are used, subject to any conditions in the Rules or the contractual arrangement on which such tool is based. DTC's Recovery Plan would consist of (1) a description of the risk management surveillance, tools, and governance that DTC would employ across evolving stress scenarios that it may face as it transitions through a "Crisis Continuum," described below; (2) a description of DTC's risk of losses that may result from non-default events, and the financial resources and recovery tools available to DTC to manage those risks and any resulting losses; and (3) an evaluation of the characteristics of the recovery tools that may be used in response to either losses arising out of a Participant Default (as defined below) or non-default losses, as described in greater detail below. In all cases, DTC would act in accordance with the Rules, within the governance structure described in the R&W Plan, and in accordance with applicable regulatory oversight to address each situation in order to best protect DTC, its

Participants and the markets in which it operates.

Managing Participant Default Losses and Liquidity Needs Through the Crisis Continuum. The Plan would describe the risk management surveillance, tools, and governance that DTC may employ across an increasing stress environment, which is referred to as the "Crisis Continuum." This description would identify those tools that can be employed to mitigate losses, and mitigate or minimize liquidity needs, as the market environment becomes increasingly stressed. The phases of the Crisis Continuum would include (1) a stable market phase, (2) a stressed market phase, (3) a phase commencing with DTC's decision to cease to act for a Participant or Affiliated Family of Participants (referred to in the Plan as the "Participant Default phase"),22 and (4) a recovery phase. This section of the Recovery Plan would address conditions and circumstances relating to DTC's decision to cease to act for a Participant pursuant to the Rules.²³ For ease of reference, the R&W Plan would, for purposes of the Plan, use the term "Participant Default Losses" to refer to losses that arise out of or relate to the Participant Default and resulting cease to act (including any losses that arise from liquidation of the Participant's Collateral).

The Recovery Plan would provide context to its roadmap through this Crisis Continuum by describing DTC's ongoing management of credit, market risk and liquidity risk, and its existing process for measuring and reporting its risks as they align with established thresholds for its tolerance of those risks. The Recovery Plan would discuss the management of credit/market risk and liquidity exposures together, because the tools that address these risks can be deployed either separately or in a coordinated approach in order to address both exposures. DTC manages these risk exposures collectively to limit their overall impact on DTC and its Participants. DTC has built-in mechanisms to limit exposures and replenish financial resources used in a

stress event, in order to continue to operate in a safe and sound manner. DTC is a closed, collateralized system in which liquidity resources are matched against risk management controls, so, at any time, the potential net settlement obligation of the Participant or Affiliated Family of Participants with the largest net settlement obligation cannot exceed the amount of liquidity resources.²⁴ While Collateral securities are subject to market price risk, DTC manages its liquidity and market risks through the calculation of the required deposits to the Participants Fund 25 and risk management controls, i.e., collateral haircuts, the Collateral Monitor 26 and Net Debit Cap.27

The Recovery Plan would outline the metrics and indicators that DTC has developed to evaluate a stress situation against established risk tolerance thresholds. Each risk mitigation tool identified in the Recovery Plan would include a description of the escalation thresholds that allow for effective and timely reporting to the appropriate internal management staff and committees, or to the Board. The Recovery Plan would make clear that these tools and escalation protocols would be calibrated across each phase of the Crisis Continuum. The Recovery Plan would also establish that DTC would retain the flexibility to deploy such tools either separately or in a coordinated approach, and to use other alternatives to these actions and tools as necessitated by the circumstances of a particular Participant Default event, in accordance with the Rules. Therefore, the Recovery Plan would both provide DTC with a roadmap to follow within each phase of the Crisis Continuum, and would permit it to adjust its risk

²¹ The Plan would state that these groups would be involved to address how to mitigate the financial impact of non-default losses, and in recommending mitigating actions, the Management Committee would consider information and recommendations from relevant subject matter experts based on the nature and circumstances of the non-default event. Any necessary operational response to these events, however, would be managed in accordance with applicable incident response/business continuity process; for example, processes established by the DTCC Technology Risk Management group would be followed in response to a cyber event.

²² The Plan defines an "Affiliated Family" of Participants as a number of affiliated entities that are all Participants of DTC.

²³ In the Plan, "cease to act" and the actions that may lead to such decision, are used within the context of the Rules, including Rule 4 (Participants Fund and Participants Investment), Rule 9(A) (Transactions in Securities and Money Payments), Rule 9(B) (Transactions in Eligible Securities), Rule 9(C) (Transactions in MMI Securities), Rule 10 (Discretionary Termination), Rule 11 (Mandatory Termination) and Rule 12 (Insolvency), *supra* note 7. Further, the term "Participant Default" would also be used in the Plan as such term is defined in Rule 4, as proposed to be amended by the Loss Allocation filing, *supra* note 12.

²⁴ DTC's liquidity risk management strategy, including the manner in which DTC would deploy liquidity tools as well as its intraday use of liquidity, is described in the Clearing Agency Liquidity Risk Management Framework. See Securities Exchange Act Release No. 80489 (April 19, 2017), 82 FR 19120 (April 25, 2017) (SR–DTC–2017–004, SR–DTC–2017–005, SR–FICC–2017–008).

 $^{^{25}\,}See$ Rule 4 (Participants Fund and Participants Investment), supra note 7.

²⁶ See Rule 1, Section 1, supra note 7. For DTC, credit risk and market risk are closely related, as DTC monitors credit exposures from Participants through these risk management controls, which limit Participant settlement obligations to the amount of available liquidity resources and require those obligations to be fully collateralized. The pledge or liquidation of collateral in an amount sufficient to restore liquidity resources depends on market values and demand, i.e., market risk exposure. Such risk management controls are part of DTC's market risk management strategy and are designed to comply with Rule 17Ad–22(e)(4) under the Act, where these risks are referred to as "credit risks." See also 17 CFR 240.17Ad–22(e)(4).

²⁷ Id.

management measures to address the unique circumstances of each event.

The Recovery Plan would describe the conditions that mark each phase of the Crisis Continuum, and would identify actions that DTC could take as it transitions through each phase in order to both prevent losses from materializing through active risk management, and to restore the financial health of DTC during a period of stress.

The stable market phase of the Crisis Continuum would describe active risk management activities in the normal course of business. These activities would include performing (1) backtests to evaluate the adequacy of the collateral level and the haircut sufficiency for covering market price volatility and (2) stress testing to cover market price moves under real historical and hypothetical scenarios to assess the haircut adequacy under extreme but plausible market conditions. The backtesting and stress testing results are escalated, as necessary, to internal and Board committees.²⁸

The Recovery Plan would describe some of the indicators of the stress market phase of the Crisis Continuum, which would include, for example, volatility in market prices of certain assets where there is increased uncertainty among market participants about the fundamental value of those assets. This phase would involve general market stresses, when no Participant Default would be imminent. Within the description of this phase, the Recovery Plan would provide that DTC may take targeted, routine risk management measures as necessary and as permitted by the Rules.

Ŵithin the Participant Default phase of the Crisis Continuum, the Recovery Plan would provide a roadmap for the existing procedures that DTC would follow in the event of a Participant Default and any decision by DTC to cease to act for that Participant.²⁹ The Recovery Plan would provide that the objectives of DTC's actions upon a Participant Default are to (1) minimize losses and market exposure, and (2), to the extent practicable, minimize disturbances to the affected markets. The Recovery Plan would describe tools, actions, and related governance for both market risk monitoring and

liquidity risk monitoring through this phase. For example, in connection with managing its market risk during this phase, DTC would, pursuant to its Rules and existing procedures, (1) monitor and assess the adequacy of its Participants Fund and Net Debit Caps; and (2) follow its operational procedures relating to the execution of a liquidation of the Defaulting Participant's Collateral securities through close collaboration and coordination across multiple functions. Management of liquidity risk through this phase would involve ongoing monitoring of, among other things, the adequacy of the Participants Fund and risk controls, and the Recovery Plan would identify certain actions DTC may deploy as it deems necessary to mitigate a potential liquidity shortfall, which would include, for example, the reduction of Net Debit Caps of some or all Participants, or seeking additional liquidity resources. The Recovery Plan would state that, throughout this phase, relevant information would be escalated and reported to both internal management committees and the Board Risk Committee.

The Recovery Plan would also identify financial resources available to DTC, pursuant to the Rules, to address losses arising out of a Participant Default. Specifically, Rule 4, as proposed to be amended by the Loss Allocation Filing, would provide that losses remaining after application of the Defaulting Participant's resources be satisfied first by applying a "Corporate Contribution," and then, if necessary, by allocating remaining losses among the membership in accordance with such Rule 4, as amended.³⁰

In order to provide for an effective and timely recovery, the Recovery Plan would describe the period of time that would occur near the end of the Participant Default phase, during which DTC may experience stress events or observe early warning indicators that allow it to evaluate its options and prepare for the recovery phase (referred to in the Plan as the "Recovery Corridor"). The Recovery Plan would then describe the recovery phase of the

Crisis Continuum, which would begin on the date that DTC issues the first Loss Allocation Notice of the second loss allocation round with respect to a given "Event Period." ³¹ The recovery phase would describe actions that DTC may take to avoid entering into a wind-down of its business.

DTC expects that significant deterioration of liquidity resources would cause it to enter the Recovery Corridor. As such, the Plan would describe the actions DTC may take aimed at replenishing those resources Recovery Corridor indicators may include, for example, a rapid and material increase in market prices or sequential or simultaneous failures of multiple Participants or Affiliated Families of Participants over a compressed time period. Throughout the Recovery Corridor, DTC would monitor the adequacy of its resources and the expected timing of replenishment of those resources, and would do so through the monitoring of certain corridor indicator metrics.

The majority of the corridor indicators, as identified in the Recovery Plan, relate directly to conditions that may require DTC to adjust its strategy for hedging and liquidating Collateral securities, and any such changes would include an assessment of the status of the corridor indicators. Corridor indicators would include, for example, effectiveness and speed of DTC's efforts to liquidate Collateral securities, and an impediment to the availability of its resources to repay any borrowings due to any Participant default. For each corridor indicator, the Recovery Plan would identify (1) measures of the indicator, (2) evaluations of the status of the indicator, (3) metrics for determining the status of the deterioration or improvement of the indicator, and (4) "Corridor Actions," which are steps that may be taken to improve the status of the indicator,³² as

²⁸ DTC's stress testing practices are described in the Clearing Agency Stress Testing Framework (Market Risk). See Securities Exchange Act Release No. 80485 (April 19, 2017), 82 FR 19131 (April 25, 2017) (SR–DTC–2017–005, SR–FICC–2017–009, SR–NSCC–2017–006).

²⁹ See Rule 10 (Discretionary Termination); Rule 11 (Mandatory Termination); Rule 12 (Insolvency), supra note 7.

³⁰ See supra note 12. The Loss Allocation Filing proposes to amend Rule 4 to define the amount DTC would contribute to address a loss resulting from either a Participant Default or a non-default event as the "Corporate Contribution." This amount would be 50 percent (50%) of the "General Business Risk Capital Requirement," which is calculated pursuant to the Capital Policy and is an amount sufficient to cover potential general business losses so that DTC can continue operations and services as a going concern if those losses materialize, in compliance with Rule 17Ad–22(e)(15) under the Act. See also supra note 10; 17 CFR 240.17Ad–22(e)(15).

³¹ The Loss Allocation Filing proposes to amend Rule 4 to introduce the concept of an "Event Period" as the ten (10) Business Days beginning on (i) with respect to a Participant Default, the day on which DTC notifies Participants that it has ceased to act for a Participant, or (ii) with respect to a nondefault loss, the day that DTC notifies Participants of the determination by the Board of Directors that there is a non-default loss event, as described in greater detail in that filing. The proposed Rule 4 would define a "round" as a series of loss allocations relating to an Event Period, and would provide that the first Loss Allocation Notice in a first, second, or subsequent round shall expressly state that such notice reflects the beginning of a first, second, or subsequent round. The maximum allocable loss amount of a round is equal to the sum of the "Loss Allocation Caps" (as defined in the proposed Rule 4) of those Participants included in the round. See supra note 12.

³² The Corridor Actions that would be identified in the Plan are indicative, but not prescriptive;

well as management escalations required to authorize those steps. Because DTC has never experienced the default of multiple Participants, it has not, historically, measured the deterioration or improvements metrics of the corridor indicators. As such, these metrics were chosen based on the business judgment of DTC management.

The Recovery Plan would also describe the reporting and escalation of the status of the corridor indicators throughout the Recovery Corridor. Significant deterioration of a corridor indicator, as measured by the metrics set out in the Recovery Plan, would be escalated to the Board. DTC management would review the corridor indicators and the related metrics at least annually, and would modify these metrics as necessary in light of observations from simulations of Participant Defaults and other analyses. Any proposed modifications would be reviewed by the Management Risk Committee and the Board Risk Committee. The Recovery Plan would estimate that DTC may remain in the Recovery Corridor stage between one day and two weeks. This estimate is based on historical data observed in past Participant Default events, the results of simulations of Participant Defaults, and periodic liquidity analyses conducted by DTC. The actual length of a Recovery Corridor would vary based on actual market conditions observed at the time, and DTC would expect the Recovery Corridor to be shorter in market conditions of increased stress.

The Recovery Plan would outline steps by which DTC may allocate its losses, which would occur when and in the order provided in Rule 4, as amended.33 The Recovery Plan would also identify tools that may be used to address foreseeable shortfalls of DTC's liquidity resources following a Participant Default, and would provide that these tools may be used as appropriate during the Crisis Continuum to address liquidity shortfalls if they arise. The goal in managing DTC's liquidity resources is to maximize resource availability in an evolving stress situation, to maintain flexibility in the order and use of sources of liquidity, and to repay any third party lenders in a timely manner.

Liquidity tools include, for example, DTC's committed 364-day credit facility ³⁴ and Net Credit Reductions. ³⁵ The Recovery Plan would state that the availability and capacity of these liquidity tools cannot be accurately predicted and are dependent on the circumstances of the applicable stress period, including market price volatility, actual or perceived disruptions in financial markets, the costs to DTC of utilizing these tools, and any potential impact on DTC's credit rating.

As stated above, the Recovery Plan would state that DTC will have entered the recovery phase on the date that it issues the first Loss Allocation Notice of the second loss allocation round with respect to a given Event Period. The Recovery Plan would provide that, during the recovery phase, DTC would continue and, as needed, enhance, the monitoring and remedial actions already described in connection with previous phases of the Crisis Continuum, and would remain in the recovery phase until its financial resources are expected to be or are fully replenished, or until the Wind-down Plan is triggered, as described below.

The Recovery Plan would describe governance for the actions and tools that may be employed within each phase of the Crisis Continuum, which would be dictated by the facts and circumstances applicable to the situation being addressed. Such facts and circumstances would be measured by the various indicators and metrics applicable to that phase of the Crisis Continuum, and would follow relevant escalation protocol that would be described in the Recovery Plan. The Recovery Plan would also describe the governance procedures around a decision to cease to act for a Participant, pursuant to the Rules, and around the management and oversight of the subsequent liquidation of Collateral securities. The Recovery Plan would state that, overall, DTC would retain flexibility in accordance with the Rules, its governance structure, and its regulatory oversight, to address a particular situation in order to best protect DTC and its Participants, and to

meet the primary objectives, throughout the Crisis Continuum, of minimizing losses and, where consistent and practicable, minimizing disturbance to affected markets.

Non-Default Losses. The Recovery Plan would outline how DTC may address losses that result from events other than a Participant Default. While these matters are addressed in greater detail in other documents, this section of the Plan would provide a roadmap to those documents and an outline for DTC's approach to monitoring and managing losses that could result from a non-default event. The Plan would first identify some of the risks DTC faces that could lead to these losses, which include, for example, the business and profit/loss risks of unexpected declines in revenue or growth of expenses; the operational risks of disruptions to systems or processes that could lead to large losses, including those resulting from, for example, a cyber-attack; and custody or investment risks that could lead to financial losses. The Recovery Plan would describe DTC's overall strategy for the management of these risks, which includes a "three lines of defense" approach to risk management that allows for comprehensive management of risk across the organization.36 The Recovery Plan would also describe DTC's approach to financial risk and capital management. The Plan would identify key aspects of this approach, including, for example, an annual budget process, business line performance reviews with management, and regular review of capital requirements against LNA. These risk management strategies are collectively intended to allow DTC to effectively identify, monitor, and manage risks of non-default losses.

therefore, if DTC needs to consider alternative actions due to the applicable facts and circumstances, the escalation of those alternative actions would follow the same escalation protocol identified in the Plan for the Corridor Indicator to which the action relates.

³³ As these matters are described in greater detail in the Loss Allocation Filing and in the proposed amendments to Rule 4, described therein, reference is made to that filing and the details are not repeated here. See supra note 12.

³⁴ See Securities Exchange Act Release No. 80605 (May 5, 2017), 82 FR 21850 (May 10, 2017) (SR– DTC–2017–802: SR–NSCC–2017–802).

³⁵DTC may borrow amounts needed to complete settlement from Participants by net credit reductions to their settlement accounts, secured by the Collateral of the defaulting Participant. See Securities Exchange Act Release Nos. 24689 (July 9, 1987), 52 FR 26613 (July 15, 1987) (SR–DTC–87–4); 41879 (September 15, 1999), 64 FR 51360 (September 22, 1999) (SR–DTC–99–15); 42281 (December 28, 1999), 65 FR 1420 (January 10, 2000) (SR–DTC–99–25).

 $^{^{36}\,\}mathrm{This}$ "three lines of defense" approach to risk management includes (1) a first line of defense comprised of the various business lines and functional units that support the products and services offered by DTC; (2) a second line of defense comprised of control functions that support DTC, including the risk management, legal and compliance areas; and (3) a third line of defense, which is performed by an internal audit group. The Clearing Agency Risk Management Framework includes a description of this "three lines of defense" approach to risk management, and addresses how DTC comprehensively manages various risks, including operational, general business, investment, custody, and other risks that arise in or are borne by it. See Securities Exchange Act Release No. 81635 (September 15, 2017), 82 FR 44224 (September 21, 2017) (SR-DTC-2017-013; SR-FICC-2017-016; SR-NSCC-2017-012). The Clearing Agency Operational Risk Management Framework describes the manner in which DTC manages operational risks, as defined therein. See Securities Exchange Act Release No. 81745 (September 28, 2017), 82 FR 46332 (October 4, 2017) (SR-DTC-2017-014; SR-FICC-2017-017; SR-NSCC-2017-013).

The Plan would identify the two categories of financial resources DTC maintains to cover losses and expenses arising from non-default risks or events as (1) LNA, maintained, monitored, and managed pursuant to the Capital Policy, which include (a) amounts held in satisfaction of the General Business Risk Capital Requirement,37 (b) the Corporate Contribution,38 and (c) other amounts held in excess of DTC's capital requirements pursuant to the Capital Policy; and (2) resources available pursuant to the loss allocation provisions of Rule 4.39

The Plan would address the process by which the CFO and the DTCC Treasury group would determine which available LNA resources are most appropriate to cover a loss that is caused by a non-default event. This determination involves an evaluation of a number of factors, including the current and expected size of the loss, the expected time horizon over when the loss or additional expenses would materialize, the current and projected available LNA, and the likelihood LNA could be successfully replenished pursuant to the Replenishment Plan, if triggered. 40 Finally the Plan would discuss how DTC would apply its resources to address losses resulting from a non-default event, including the order of resources it would apply if the loss or liability is expected to exceed DTC's excess LNA amounts, or is large relative thereto, and the Board has declared the event a "Declared Non-Default Loss Event" pursuant to Rule

The Plan would also describe proposed Rule 38 (Market Disruption and Force Majeure), which DTC is proposing to adopt in its Rules. This Proposed Rule would provide transparency around how DTC would address extraordinary events that may occur outside its control. Specifically, the Proposed Rule would define a "Market Disruption Event" and the governance around a determination that such an event has occurred. The Proposed Rule would also describe DTC's authority to take actions during the pendency of a Market Disruption Event that it deems appropriate to address such an event and facilitate the continuation of its services, if practicable, as described in greater detail below.

The Plan would describe the interaction between the Proposed Rule

and DTC's existing processes and procedures addressing business continuity management and disaster recovery (generally, the "BCM/DR procedures"), making clear that the Proposed Rule is designed to support those BCM/DR procedures and to address circumstances that may be exogenous to DTC and not necessarily addressed by the BCM/DR procedures. Finally, the Plan would describe that, because the operation of the Proposed Rule is specific to each applicable Market Disruption Event, the Proposed Rule does not define a time limit on its application. However, the Plan would note that actions authorized by the Proposed Rule would be limited to the pendency of the applicable Market Disruption Event, as made clear in the Proposed Rule. Overall, the Proposed Rule is designed to mitigate risks caused by Market Disruption Events and, thereby, minimize the risk of financial loss that may result from such events.

Recovery Tool Characteristics. The Recovery Plan would describe DTC's evaluation of the tools identified within the Recovery Plan, and its rationale for concluding that such tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to Participants and minimize negative impact on Participants and the financial system, in compliance with guidance published by the Commission in connection with the adoption of Rule 17Ad-22(e)(3)(ii) under the Act.⁴² DTC's analysis and the conclusions set forth in this section of the Recovery Plan are described in greater detail in Item 3(b) of this filing, below.

DTC Wind-Down Plan

The Wind-down Plan would provide the framework and strategy for the orderly wind-down of DTC if the use of the recovery tools described in the Recovery Plan do not successfully return DTC to financial viability. While DTC believes that, given the comprehensive nature of the recovery tools, such event is extremely unlikely, as described in greater detail below, DTC is proposing a wind-down strategy that provides for (1) the transfer of DTC's business, assets, securities inventory, and membership to another legal entity, (2) such transfer being effected in connection with proceedings under Chapter 11 of the U.S. Federal Bankruptcy Code,43 and (3) after effectuating this transfer, DTC

liquidating any remaining assets in an orderly manner in bankruptcy proceedings. DTC believes that the proposed transfer approach to a winddown would meet its objectives of (1) assuring that DTC's critical services will be available to the market as long as there are Participants in good standing, and (2) minimizing disruption to the operations of Participants and financial markets generally that might be caused by DTC's failure.

In describing the transfer approach to DTC's Wind-down Plan, the Plan would identify the factors that DTC considered in developing this approach, including the fact that DTC does not own material assets that are unrelated to its clearance and settlement activities. As such, a business reorganization or "bail-in" of debt approach would be unlikely to mitigate significant losses. Additionally, DTC's approach was developed in consideration of its critical and unique position in the U.S. markets, which precludes any approach that would cause DTC's critical services to no

longer be available.

First, the Wind-down Plan would describe the potential scenarios that could lead to the wind-down of DTC, and the likelihood of such scenarios. The Wind-down Plan would identify the time period leading up to a decision to wind-down DTC as the "Runway Period." This period would follow the implementation of any recovery tools, as it may take a period of time, depending on the severity of the market stress at that time, for these tools to be effective or for DTC to realize a loss sufficient to cause it to be unable to borrow to complete settlement and to repay such borrowings.44 The Plan would identify some of the indicators that DTC has entered this Runway Period, which would include, for example, simultaneous successive Participant Defaults, significant Participant retirements, and DTC's inability to replenish financial resources following the liquidation of Collateral securities.

The trigger for implementing the Wind-down Plan would be a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning DTC to viability as a going concern. As described in the Plan, DTC believes this is an appropriate trigger because it is both broad and flexible enough to cover

³⁷ See supra note 30.

³⁸ See supra note 30.

³⁹ See supra note 12.

⁴⁰ See supra note 10.

⁴¹ See supra note 12.

⁴² Standards for Covered Clearing Agencies, Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7-03-14).

^{43 11} U.S.C. 1101 et seq.

⁴⁴ The Wind-down Plan would state that, given DTC's position as a user-governed financial market utility, it is possible that its Participants might voluntarily elect to provide additional support during the recovery phase leading up to a potential trigger of the Wind-down Plan, but would also make clear that DTC cannot predict the willingness of Participants to do so.

a variety of scenarios, and would align incentives of DTC and Participants to avoid actions that might undermine DTC's recovery efforts. Additionally, this approach takes into account the characteristics of DTC's recovery tools and enables the Board to consider (1) the presence of indicators of a successful or unsuccessful recovery, and (2) potential for knock-on effects of continued iterative application of DTC's recovery tools.

The Wind-down Plan would describe the general objectives of the transfer strategy, and would address assumptions regarding the transfer of DTC's critical services, business, assets, securities inventory, and membership 45 to another legal entity that is legally, financially, and operationally able to provide DTC's critical services to entities that wish to continue their membership following the transfer ("Transferee"). The Wind-down Plan would provide that the Transferee would be either (1) a third party legal entity, which may be an existing or newly established legal entity or a bridge entity formed to operate the business on an interim basis to enable the business to be transferred subsequently ("Third Party Transferee"); or (2) an existing, debt-free failover legal entity established ex-ante by DTCC ("Failover Transferee") to be used as an alternative Transferee in the event that no viable or preferable Third Party Transferee timely commits to acquire DTC's business. DTC would seek to identify the proposed Transferee, and negotiate and enter into transfer arrangements during the Runway Period and prior to making any filings under Chapter 11 of the U.S. Federal Bankruptcy Code. 46 As stated above, the Wind-down Plan would anticipate that the transfer to the Transferee, including the transfer and establishment of the Participant and Pledgee securities accounts on the books of the Transferee, be effected in connection with proceedings under Chapter 11 of the U.S. Federal Bankruptcy Code, and pursuant to a bankruptcy court order under Section 363 of the Bankruptcy Code, such that the transfer would be free and clear of claims against, and interests in, DTC, except to the extent expressly provided in the court's order.47

In order to effect a timely transfer of its services and minimize the market and operational disruption of such transfer, DTC would expect to transfer all of its critical services and any noncritical services that are ancillary and beneficial to a critical service, or that otherwise have substantial user demand from the continuing membership. Given the transfer of the securities inventory and the establishment on the books of the Transferee Participant and Pledgee securities accounts, DTC anticipates that, following the transfer, it would not itself continue to provide any services, critical or not. Following the transfer, the Wind-down Plan would anticipate that the Transferee and its continuing membership would determine whether to continue to provide any transferred non-critical service on an ongoing basis, or terminate the non-critical service following some transition period. DTC's Wind-down Plan would anticipate that the Transferee would enter into a transition services agreement with DTCC so that DTCC would continue to provide the shared services it currently provides to DTC, including staffing, infrastructure and operational support. The Wind-down Plan would also anticipate the assignment of DTC's "inbound" link arrangements to the Transferee. The Wind-down Plan would provide that in the case of "outbound" links, DTC would seek to have the linked FMIs agree, at a minimum, to accept the Transferee as a link party for a transition period.48

The Wind-down Plan would provide that, following the effectiveness of the transfer to the Transferee, the wind-down of DTC would involve addressing any residual claims against DTC through the bankruptcy process and liquidating the legal entity. As such, and as stated above, the Wind-down Plan does not contemplate DTC continuing to provide services in any capacity following the transfer time, and any services not transferred would be terminated.

The Wind-down Plan would also identify the key dependencies for the effectiveness of the transfer, which include regulatory approvals that would permit the Transferee to be legally qualified to provide the transferred

services from and after the transfer, and approval by the applicable bankruptcy court of, among other things, the proposed sale, assignments, and transfers to the Transferee.

The Wind-down Plan would address governance matters related to the execution of the transfer of DTC's business and its wind-down. The Winddown Plan would address the duties of the Board to execute the wind-down of DTC in conformity with (1) the Rules, (2) the Board's fiduciary duties, which mandate that it exercise reasonable business judgment in performing these duties, and (3) DTC's regulatory obligations under the Act as a registered clearing agency. The Wind-down Plan would also identify certain factors the Board may consider in making these decisions, which would include, for example, whether DTC could safely stabilize the business and protect its value without seeking bankruptcy protection, and DTC's ability to continue to meet its regulatory requirements.

The Wind-down Plan would describe (1) actions DTC or DTCC may take to prepare for wind-down in the period before DTC experiences any financial distress, (2) actions DTC would take both during the recovery phase and the Runway Period to prepare for the execution of the Wind-down Plan, and (3) actions DTC would take upon commencement of bankruptcy proceedings to effectuate the Wind-down Plan.

Finally, the Wind-down Plan would include an analysis of the estimated time and costs to effectuate the plan, and would provide that this estimate be reviewed and approved by the Board annually. In order to estimate the length of time it might take to achieve a recovery or orderly wind-down of DTC's critical operations, as contemplated by the R&W Plan, the Wind-down Plan would include an analysis of the possible sequencing and length of time it might take to complete an orderly wind-down and transfer of critical operations, as described in earlier sections of the R&W Plan. The Winddown Plan would also include in this analysis consideration of other factors, including the time it might take to complete any further attempts at recovery under the Recovery Plan. The Wind-down Plan would then multiply this estimated length of time by DTC's average monthly operating expenses, including adjustments to account for changes to DTC's profit and expense profile during these circumstances, over the previous twelve months to determine the amount of LNA that it should hold to achieve a recovery or

⁴⁵ Arrangements with FAST Agents and DRS Agents (each as defined in proposed Rule 32(A)) and with Settling Banks would also be assigned to the Transferee, so that the approach would be transparent to issuers and their transfer agents, as well as to Settling Banks.

⁴⁶ 11 U.S.C. 1101 et seq.

⁴⁷ See id. at 363.

⁴⁸ The proposed transfer arrangements outlined in the Wind-down Plan do not contemplate the transfer of any credit or funding agreements, which are generally not assignable by DTC. However, to the extent the Transferee adopts rules substantially identical to those DTC has in effect prior to the transfer, it would have the benefit of any rulesbased liquidity funding. The Wind-down Plan contemplates that no Participants Fund would be transferred to the Transferee, as it is not held in a bankruptcy remote manner and it is the primary prefunded liquidity resource to be accessed in the recovery phase.

orderly wind-down of DTC's critical operations. The estimated wind-down costs would constitute the "Recovery/Wind-down Capital Requirement" under the Capital Policy. 49 Under that policy, the General Business Risk Capital Requirement is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement. 50

The R&W Plan is designed as a roadmap, and the types of actions that may be taken both leading up to and in connection with implementation of the Wind-down Plan would be primarily addressed in other supporting documentation referred to therein.

The Wind-down Plan would address proposed Rule 32(A) (Wind-down of the Corporation and proposed Rule 38 (Force Majeure and Market Disruption)), which would be adopted to facilitate the implementation of the Wind-down Plan, as discussed below.

Proposed Rules

In connection with the adoption of the R&W Plan, DTC is proposing to adopt the Proposed Rules, each described below. The Proposed Rules would facilitate the execution of the R&W Plan and would provide Participants with transparency as to critical aspects of the Plan, particularly as they relate to the rights and responsibilities of both DTC and its Participants. The Proposed Rules also provide a legal basis to these aspects of the Plan.

Rule 32(A) (Wind-Down of the Corporation)

The proposed Rule 32(A) ("Winddown Rule") would be adopted to facilitate the execution of the Winddown Plan. The Wind-down Rule would include a proposed set of defined terms that would be applicable only to the provisions of this Proposed Rule. The Wind-down Rule would make clear that a wind-down of DTC's business would occur (1) after a decision is made by the Board, and (2) in connection with the transfer of DTC's services to a Transferee, as described therein. Generally, the proposed Wind-down Rule is designed to create clear mechanisms for the transfer of Eligible Participants and Pledgees, Settling Banks, DRS Agents, and FAST Agents (as these terms would be defined in the Wind-down Rule), and DTC's inventory of financial assets in order to provide for continued access to critical services and to minimize disruption to the markets in

Wind-down Trigger. First, the Proposed Rule would make clear that the Board is responsible for initiating the Wind-down Plan, and would identify the criteria the Board would consider when making this determination. As provided for in the Wind-down Plan and in the proposed Wind-down Rule, the Board would initiate the Plan if, in the exercise of its business judgment and subject to its fiduciary duties, it has determined that the execution of the Recovery Plan has not or is not likely to restore DTC to viability as a going concern, and the implementation of the Wind-down Plan, including the transfer of DTC's business, is in the best interests of DTC, its Participants and Pledgees, its shareholders and creditors, and the U.S. financial markets.

Identification of Critical Services; Designation of Dates and Times for Specific Actions. The Proposed Rule would provide that, upon making a determination to initiate the Winddown Plan, the Board would identify the critical and non-critical services that would be transferred to the Transferee at the Transfer Time (as defined below and in the Proposed Rule), as well as any non-critical services that would not be transferred to the Transferee. The proposed Wind-down Rule would establish that any services transferred to the Transferee will only be provided by the Transferee as of the Transfer Time, and that any non-critical services that are not transferred to the Transferee would be terminated at the Transfer Time. The Proposed Rule would also provide that the Board would establish (1) an effective time for the transfer of DTC's business to a Transferee ("Transfer Time"), and (2) the last day that instructions in respect of securities and other financial products may be effectuated through the facilities of DTC (the "Last Activity Date"). The Proposed Rule would make clear that DTC would not accept any transactions for settlement after the Last Activity Date. Any transactions to be settled after the Transfer Time would be required to be submitted to the Transferee, and would not be DTC's responsibility.

Notice Provisions. The proposed Wind-down Rule would provide that, upon a decision to implement the Winddown Plan, DTC would provide its Participants, Pledgees, DRS Agents, FAST Agents, Settling Banks and regulators with a notice that includes material information relating to the Wind-down Plan and the anticipated transfer of DTC's Participants and business, including, for example, (1) a

brief statement of the reasons for the decision to implement the Wind-down Plan; (2) identification of the Transferee and information regarding the transaction by which the transfer of DTC's business would be effected: (3) the Transfer Time and Last Activity Date; and (4) identification of Participants and the critical and noncritical services that would be transferred to the Transferee at the Transfer Time, as well as those Non-Eligible Participants (as defined below and in the Proposed Rule) and any noncritical services that would not be included in the transfer. DTC would also make available the rules and procedures and membership agreements of the Transferee.

Transfer of Membership. The proposed Wind-down Rule would address the expected transfer of DTC's membership to the Transferee, which DTC would seek to effectuate by entering into an arrangement with a Failover Transferee, or by using commercially reasonable efforts to enter into such an arrangement with a Third Party Transferee. Thus, under the proposal, in connection with the implementation of the Wind-down Plan and with no further action required by any party:

(1) Each Eligible Participant would become (i) a Participant of the Transferee and (ii) a party to a Participants agreement with the Transferee;

(2) each Participant that is delinquent in the performance of any obligation to DTC or that has provided notice of its election to withdraw as a Participant (a "Non-Eligible Participant") as of the Transfer Time would become (i) the holder of a transition period securities account maintained by the Transferee on its books ("Transition Period Securities Account") and (ii) a party to a Transition Period Securities Account agreement of the Transferee;

- (3) each Pledgee would become (i) a Pledgee of the Transferee and (ii) a party to a Pledgee agreement with the Transferee:
- (4) each DRS Agent would become (i) a DRS Agent of the Transferee and (ii) a party to a DRS Agent agreement with the Transferee;
- (5) each FAST Agent would become (i) a FAST Agent of the Transferee and (ii) a party to a FAST Agent agreement with the Transferee; and
- (6) each Settling Bank for Participants and Pledgees would become (i) a Settling Bank for Participants and Pledgees of the Transferee and (ii) a party to a Settling Bank Agreement with the Transferee.

the event the Wind-down Plan is initiated.

⁴⁹ See supra note 10.

⁵⁰ See supra note 10.

Further, the Proposed Rule would make clear that it would not prohibit (1) Non-Eligible Participants from applying for membership with the Transferee, (2) Non-Eligible Participants that have become holders of Transition Period Securities Accounts ("Transition Period Securities Account Holders") of the Transferee from withdrawing as a Transition Period Securities Account Holder from the Transferee, subject to the rules and procedures of the Transferee, and (3) Participants, Pledgees, DRS Agents, FAST Agents, and Settling Banks that would be transferred to the Transferee from withdrawing from membership with the Transferee, subject to the rules and procedures of the Transferee. Under the Proposed Rule, Non-Eligible Participants that have become Transition Period Securities Account Holders of the Transferee shall have the rights and be subject to the obligations of Transition Period Securities Account Holders set forth in special provisions of the rules and procedures of the Transferee applicable to such Transition Period Securities Account Holder. Specifically, Non-Eligible Participants that become Transition Period Securities Account Holders must, within the Transition Period (as defined in the Proposed Rule), instruct the Transferee to transfer the financial assets credited to its Transition Period Securities Account (i) to a Participant of the Transferee through the facilities of the Transferee or (ii) to a recipient outside the facilities of the Transferee, and no additional financial assets may be delivered versus payment to a Transition Period Securities Account during the Transition Period.

Transfer of Inventory of Financial Assets. The proposed Wind-down Rule would provide that DTC would enter into arrangements with a Failover Transferee, or would use commercially reasonable efforts to enter into arrangements with a Third Party Transferee, providing that, in either

case, at Transfer Time:

(1) DTC would transfer to the Transferee (i) its rights with respect to its nominee Cede & Co. ("Cede") (and thereby its rights with respect to the financial assets owned of record by Cede), (ii) the financial assets held by it at the FRBNY, (iii) the financial assets held by it at other CSDs, (iv) the financial assets held in custody for it with FAST Agents, (v) the financial assets held in custody for it with other custodians and (vi) the financial assets it holds in physical custody.

(2) The Transferee would establish security entitlements on its books for Eligible Participants of DTC that become Participants of the Transferee that replicate the security entitlements that DTC maintained on its books immediately prior to the Transfer Time for such Eligible Participants, and DTC would simultaneously eliminate such security entitlements from its books.

(3) The Transferee would establish security entitlements on its books for Non-Eligible Participants of DTC that become Transition Period Securities Account Holders of the Transferee that replicate the security entitlements that DTC maintained on its books immediately prior to the Transfer Time for such Non-Eligible Participants, and DTC would simultaneously eliminate such security entitlements from its books.

(4) The Transferee would establish pledges on its books in favor of Pledgees that become Pledgees of the Transferee that replicate the pledges that DTC maintained on its books immediately prior to the Transfer Time in favor of such Pledgees, and DTC shall simultaneously eliminate such pledges from its books.

Comparability Period. The proposed automatic mechanism for the transfer of DTC's membership is intended to provide DTC's membership with continuous access to critical services in the event of DTC's wind-down, and to facilitate the continued prompt and accurate clearance and settlement of securities transactions. Further to this goal, the proposed Wind-down Rule would provide that DTC would enter into arrangements with a Failover Transferee, or would use commercially reasonable efforts to enter into arrangements with a Third Party Transferee, providing that, in either case, with respect to the critical services and any non-critical services that are transferred from DTC to the Transferee, for at least a period of time to be agreed upon ("Comparability Period"), the business transferred from DTC to the Transferee would be operated in a manner that is comparable to the manner in which the business was previously operated by DTC. Specifically, the proposed Wind-down Rule would provide that: (1) The rules of the Transferee and terms of Participant, Pledgee, DRS Agent, FAST Agent and Settling Bank agreements would be comparable in substance and effect to the analogous Rules and agreements of DTC, (2) the rights and obligations of any Participants, Pledgees, DRS Agents, FAST Agents, and Settling Banks that are transferred to the Transferee would be comparable in substance and effect to their rights and obligations as to DTC, and (3) the Transferee would operate the

transferred business and provide any services that are transferred in a comparable manner to which such services were provided by DTC.

The purpose of these provisions and the intended effect of the proposed Wind-down Rule is to facilitate a smooth transition of DTC's business to a Transferee and to provide that, for at least the Comparability Period, the Transferee (1) would operate the transferred business in a manner that is comparable in substance and effect to the manner in which the business was operated by DTC, and (2) would not require sudden and disruptive changes in the systems, operations and business practices of the new Participants, Pledgees, DRS Agents, FAST Agents, and Settling Banks of the Transferee.

Subordination of Claims Provisions and Miscellaneous Matters. The proposed Wind-down Rule would also include a provision addressing the subordination of unsecured claims against DTC of its Participants who fail to participate in DTC's recovery efforts (i.e., such firms are delinquent in their obligations to DTC or elect to retire from DTC in order to minimize their obligations with respect to the allocation of losses, pursuant to the Rules). This provision is designed to incentivize Participants to participate in DTC's recovery efforts.⁵¹

The proposed Wind-down Rule would address other ex-ante matters, including provisions providing that its Participants, Pledgees, DRS Agents, FAST Agents and Settling Banks (1) will assist and cooperate with DTC to effectuate the transfer of DTC's business to a Transferee, (2) consent to the provisions of the rule, and (3) grant DTC power of attorney to execute and deliver on their behalf documents and instruments that may be requested by the Transferee. Finally, the Proposed Rule would include a limitation of liability for any actions taken or omitted to be taken by DTC pursuant to the Proposed Rule. The purpose of the limitation of liability is to facilitate and protect DTC's ability to act expeditiously in response to extraordinary events. As noted, such limitation of liability would be available only following triggering of the Winddown Plan. In addition, and as a separate matter, the limitation of

⁵¹ Nothing in the proposed Wind-down Rule would seek to prevent a Participant that retired its membership at DTC from applying for membership with the Transferee. Once its DTC membership is terminated, however, such firm would not be able to benefit from the membership assignment that would be effected by this proposed Wind-down Rule, and it would have to apply for membership directly with the Transferee, subject to its membership application and review process.

liability provides Participants with transparency for the unlikely situation when those extraordinary events could occur, as well supporting the legal framework within which DTC would take such actions. These provisions, collectively, are designed to enable DTC to take such acts as the Board determines necessary to effectuate an orderly transfer and wind-down of its business should recovery efforts prove unsuccessful.

Rule 38 (Market Disruption and Force Majeure)

The proposed Rule 38 ("Force Majeure Rule'') would address DTC's authority to take certain actions upon the occurrence, and during the pendency, of a "Market Disruption Event," as defined therein. The Proposed Rule is designed to clarify DTC's ability to take actions to address extraordinary events outside of the control of DTC and of its membership, and to mitigate the effect of such events by facilitating the continuity of services (or, if deemed necessary, the temporary suspension of services). To that end, under the proposed Force Majeure Rule, DTC would be entitled, during the pendency of a Market Disruption Event, to (1) suspend the provision of any or all services, and (2) take, or refrain from taking, or require its Participants and Pledgees to take, or refrain from taking, any actions it considers appropriate to address, alleviate, or mitigate the event and facilitate the continuation of DTC's services as may be practicable.

The proposed Force Majeure Rule would identify the events or circumstances that would be considered a "Market Disruption Event," including, for example, events that lead to the suspension or limitation of trading or banking in the markets in which DTC operates, or the unavailability or failure of any material payment, bank transfer, wire or securities settlement systems. The proposed Force Majeure Rule would define the governance procedures for how DTC would determine whether, and how, to implement the provisions of the rule. A determination that a Market Disruption Event has occurred would generally be made by the Board, but the Proposed Rule would provide for limited, interim delegation of authority to a specified officer or management committee if the Board would not be able to take timely action. In the event such delegated authority is exercised, the proposed Force Majeure Rule would require that the Board be convened as promptly as practicable, no later than five Business Days after such determination has been made, to ratify, modify, or rescind the

action. The proposed Force Majeure Rule would also provide for prompt notification to the Commission, and advance consultation with Commission staff, when practicable, including notification when an event is no longer continuing and the relevant actions are terminated. The Proposed Rule would require Participants and Pledgees to notify DTC immediately upon becoming aware of a Market Disruption Event, and, likewise, would require DTC to notify its Participants and Pledgees if it has triggered the Proposed Rule and of actions taken or intended to be taken thereunder.

Finally, the Proposed Rule would address other related matters, including a limitation of liability for any failure or delay in performance, in whole or in part, arising out of the Market Disruption Event. The purpose of the limitation of liability would be similar to the purpose of the analogous provision in the proposed Wind-down Rule, which is to facilitate and protect DTC's ability to act expeditiously in response to extraordinary events.

(a) Statutory Basis

DTC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a registered clearing agency. In particular, DTC believes that the R&W Plan and each of the Proposed Rules are consistent with Section 17A(b)(3)(F) of the Act,⁵² the R&W Plan and each of the Proposed Rules are consistent with Rule 17Ad–22(e)(3)(ii) under the Act,⁵³ and the R&W Plan is consistent with Rule 17Ad–22(e)(15)(ii) under the Act,⁵⁴ for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of DTC be designed to promote the prompt and accurate clearance and settlement of securities transactions, and to assure the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible.⁵⁵ The Recovery Plan and the proposed Force Majeure Rule would promote the prompt and accurate clearance and settlement of securities transactions by providing DTC with a roadmap for actions it may employ to mitigate losses, and monitor and, as needed, stabilize, its financial condition, which would allow it to continue its critical clearance and settlement services in stress situations. Further, as described above, the Recovery Plan is designed to

identify the actions and tools DTC may use to address and minimize losses to both DTC and its Participants. The Recovery Plan and the proposed Force Majeure Rule would provide DTC's management and the Board with guidance in this regard by identifying the indicators and governance around the use and application of such tools to enable them to address stress situations in a manner most appropriate for the circumstances. Therefore, the Recovery Plan and the proposed Force Majeure Rule would also contribute to the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible by enabling actions that would address and minimize losses.

The Wind-down Plan and the proposed Wind-down Rule, which would facilitate the implementation of the Wind-down Plan, would also promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible. The Wind-down Plan and the proposed Wind-down Rule would collectively establish a framework for the transfer and orderly wind-down of DTC's business. These proposals would establish clear mechanisms for the transfer of DTC's critical services and membership as well as clear provision for the transfer of the securities inventory it holds in fungible bulk for Participants. By doing so, the Wind-down Plan and these Proposed Rules are designed to facilitate the continuity of DTC's critical services and enable its Participants and Pledgees to maintain access to DTC's services through the transfer of its membership in the event DTC defaults or the Winddown Plan is triggered by the Board. Therefore, by facilitating the continuity of DTC's critical clearance and settlement services, DTC believes the proposals would promote the prompt and accurate clearance and settlement of securities transactions. Further, by creating a framework for the transfer and orderly wind-down of DTC's business, DTC believes the proposals would enhance the safeguarding of securities and funds which are in the custody or control of DTC or for which it is responsible.

Therefore, DTC believes the R&W Plan and each of the Proposed Rules are consistent with the requirements of Section 17A(b)(3)(F) of the Act.⁵⁶

Rule 17Ad–22(e)(3)(ii) under the Act requires DTC to establish, implement, maintain and enforce written policies

^{52 15} U.S.C. 78q-1(b)(3)(F).

^{53 17} CFR 240.17Ad-22(e)(3)(ii).

⁵⁴ Id. at 240.17Ad-22(e)(15)(ii).

^{55 15} U.S.C. 78q-1(b)(3)(F).

and procedures reasonably designed to maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by the covered clearing agency, which includes plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.57 The R&W Plan and each of the Proposed Rules are designed to meet the requirements of Rule 17Ad-22(e)(3)(ii).

The R&W Plan would be maintained by DTC in compliance with Rule 17Ad-22(e)(3)(ii) in that it provides plans for the recovery and orderly wind-down of DTC necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, as described above.⁵⁸ Specifically, the Recovery Plan would define the risk management activities, stress conditions and indicators, and tools that DTC may use to address stress scenarios that could eventually prevent it from being able to provide its critical services as a going concern. Through the framework of the Crisis Continuum, the Recovery Plan would address measures that DTC may take to address risks of credit losses and liquidity shortfalls, and other losses that could arise from a Participant Default. The Recovery Plan would also address the management of general business risks and other non-default risks that could lead to losses.

The Wind-down Plan would be triggered by a determination by the Board that recovery efforts have not been, or are unlikely to be, successful in returning DTC to viability as a going concern. Once triggered, the Winddown Plan would set forth clear mechanisms for the transfer of DTC's membership and business, and would be designed to facilitate continued access to DTC's critical services and to minimize market impact of the transfer. By establishing the framework and strategy for the execution of the transfer and wind-down of DTC in order to facilitate continuous access to DTC's critical services, the Wind-down Plan establishes a plan for the orderly winddown of DTC. Therefore, DTC believes the R&W Plan would provide plans for the recovery and orderly wind-down of the covered clearing agency necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses, and, as such, meets the

requirements of Rule 17Ad–22(e)(3)(ii).⁵⁹

As described in greater detail above, the Proposed Rules are designed to facilitate the execution of the R&W Plan, provide Participants with transparency regarding the material provisions of the Plan, and provide DTC with a legal basis for implementation of those provisions. As such, DTC also believes the Proposed Rules meet the requirements of Rule 17Ad–22(e)(3)(ii).⁶⁰

DTC has evaluated the recovery tools that would be identified in the Recovery Plan and has determined that these tools are comprehensive, effective, and transparent, and that such tools provide appropriate incentives to DTC's Participants to manage the risks they present. The recovery tools, as outlined in the Recovery Plan and in the proposed Force Majeure Rule, provide DTC with a comprehensive set of options to address its material risks and support the resiliency of its critical services under a range of stress scenarios. DTC also believes the recovery tools are effective, as DTC has both legal basis and operational capability to execute these tools in a timely and reliable manner. Many of the recovery tools are provided for in the Rules; Participants are bound by the Rules through their Participants Agreements with DTC, and the Rules are adopted pursuant to a framework established by Rule 19b-4 under the Act,61 providing a legal basis for the recovery tools found therein. Other recovery tools have legal basis in contractual arrangements to which DTC is a party, as described above. Further, as many of the tools are embedded in DTC's ongoing risk management practices or are embedded into its predefined default-management procedures, DTC is able to execute these tools, in most cases, when needed and without material operational or organizational delay.

The majority of the recovery tools are also transparent, as they are or are proposed to be included in the Rules, which are publicly available. DTC believes the recovery tools also provide appropriate incentives to its owners and Participants, as they are designed to control the amount of risk they present to DTC's clearance and settlement system. Finally, DTC's Recovery Plan provides for a continuous evaluation of the systemic consequences of executing its recovery tools, with the goal of minimizing their negative impact. The Recovery Plan would outline various

Therefore, DTC believes the R&W Plan and each of the Proposed Rules are consistent with Rule 17Ad–22(e)(3)(ii).⁶³

Rule 17Ad-22(e)(15)(ii) under the Act requires DTC to establish, implement, maintain and enforce written policies and procedures reasonably designed to identify, monitor, and manage its general business risk and hold sufficient LNA to cover potential general business losses so that DTC can continue operations and services as a going concern if those losses materialize, including by holding LNA equal to the greater of either (x) six months of the covered clearing agency's current operating expenses, or (y) the amount determined by the board of directors to be sufficient to ensure a recovery or orderly wind-down of critical operations and services of the covered clearing agency.⁶⁴ While the Capital Policy addresses how DTC holds LNA in compliance with these requirements, the Wind-down Plan would include an analysis that would estimate the amount of time and the costs to achieve a recovery or orderly wind-down of DTC's critical operations and services, and would provide that the Board review and approve this analysis and estimation annually. The Wind-down Plan would also provide that the estimate would be the "Recovery/Winddown Capital Requirement" under the Capital Policy. Under that policy, the General Business Risk Capital Requirement, which is the sufficient amount of LNA that DTC should hold to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize, is calculated as the greatest of three estimated amounts, one of which is this Recovery/Wind-down Capital Requirement. Therefore, DTC believes the R&W Plan, as it interrelates

indicators over a timeline of increasing stress, the Crisis Continuum, with escalation triggers to DTC management or the Board, as appropriate. This approach would allow for timely evaluation of the situation and the possible impacts of the use of a recovery tool in order to minimize the negative effects of the stress scenario. Therefore, DTC believes that the recovery tools that would be identified and described in its Recovery Plan, including the authority provided to it in the proposed Force Majeure Rule, would meet the criteria identified within guidance published by the Commission in connection with the adoption of Rule 17Ad-22(e)(3)(ii).62

^{57 17} CFR 240.17Ad-22(e)(3)(ii).

⁵⁸ Id.

⁵⁹ Id.

⁶⁰ *Id.* 61 *Id.* at 240.19b–4.

⁶² Supra note 42.

^{63 17} CFR 240.17Ad-22(e)(3)(ii).

⁶⁴ Id. at 240.17Ad-22(e)(15)(ii).

with the Capital Policy, is consistent with Rule 17Ad–22(e)(15)(ii).⁶⁵

(B) Clearing Agency's Statement on Burden on Competition

DTC does not believe the proposal would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purpose of the Act.⁶⁶ The proposal would apply uniformly to all Participants and Pledgees. DTC does not anticipate that the proposal would affect its day-to-day operations under normal circumstances, or in the management of a typical Participant default scenario or non-default event. DTC is not proposing to alter the standards or requirements for becoming or remaining a Participant or Pledgee, or otherwise using its services. DTC also does not propose to change its methodology for calculation of Participants Fund contributions. The proposal is intended to (1) address the risk of loss events and identify the tools and resources available to it to withstand and recover from such events, so that it can restore normal operations, and (2) provide a framework for its orderly wind-down and the transfer of its business in the event those recovery tools do not restore DTC to financial viability, as described herein.

The Ř&W Plan and each of the Proposed Rules have been developed and documented in order to satisfy applicable regulatory requirements, as discussed above.

With respect to the Recovery Plan, the proposal generally reflects DTC's existing tools and existing internal procedures. Existing tools that would have a direct impact on the rights, responsibilities or obligations of Participants are reflected in the existing Rules or are proposed to be included in the Rules. Accordingly, the Recovery Plan and the proposed Force Majeure Rule are intended to provide a roadmap, define the strategy and identify the tools available to DTC in connection with its recovery efforts. By proposing to enhance DTC's existing internal management and its regulatory compliance related to its recovery efforts, DTC does not believe the Recovery Plan or the proposed Force Majeure Rule would have any impact, or impose any burden, on competition.

With respect to the Wind-down Plan and the proposed Wind-down Rule, which facilitate the execution of the Wind-down Plan, the proposal would operate to effect the transfer of all eligible Participants and Pledgees to the Transferee, and would not prohibit any (C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

While DTC has not solicited or received any written comments relating to this proposal, DTC has conducted outreach to its Members in order to provide them with notice of the proposal. DTC will notify the Commission of any written comments received by DTC.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. 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–DTC–2017–021 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-DTC-2017-021. 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 website (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 website 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 DTC and on DTCC's website (http://dtcc.com/legal/sec-rulefilings.aspx). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-DTC-2017-021 and should be submitted on or before August 3, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority. 67

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15363 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Regulation AC; SEC File No. 270–517, OMB Control No. 3235–0575

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (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 previously approved collection of information provided for in Regulation Analyst Certification ("Regulation AC") (17 CFR 242.500–505), under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.).

Regulation AC requires that research reports published, circulated, or provided by a broker or dealer or covered person contain a statement attesting that the views expressed in each research report accurately reflect

market participant from either bidding to become the Transferee or from applying for membership with the Transferee. The proposal also would not prohibit any Participant or Pledgee from withdrawing from DTC prior to the Transfer Time, as is permitted under the Rules today, or from applying for membership with the Transferee. Therefore, as the proposal would treat each similarly situated Participant and Pledgee identically under the Winddown Plan and under the Proposed Wind-down Rule, DTC does not believe the Wind-down Plan or the proposed Wind-down Rule would have any impact, or impose any burden, on competition.

⁶⁵ *Id*.

^{66 15} U.S.C. 78q-1(b)(3)(I).

^{67 17} CFR 200.30–3(a)(12).

the analyst's personal views and whether or not the research analyst received or will receive any compensation in connection with the views or recommendations expressed in the research report. Regulation AC also requires broker-dealers to, on a quarterly basis, make, keep, and maintain records of research analyst statements regarding whether the views expressed in public appearances accurately reflected the analyst's personal views, and whether any part of the analyst's compensation is related to the specific

recommendations or views expressed in the public appearance. Regulation AC also requires that research prepared by foreign persons be presented to U.S. persons pursuant to Securities Exchange Act Rule 15a–6 and that broker-dealers notify associated persons if they would be covered by the regulation. Regulation AC excludes the news media from its coverage.

The collections of information under Regulation AC are necessary to provide investors with information with which to determine the value of the research available to them. It is important for an investor to know whether an analyst may be biased with respect to securities or issuers that are the subject of a research report. Further, in evaluating a research report, it is reasonable for an investor to want to know about an analyst's compensation. Without the information collection, the purposes of Regulation AC could not be met. This regulation does not involve the collection of confidential information.

The Commission estimates that Regulation AC imposes an aggregate annual time burden of approximately 25,844 hours on 5,186 respondents, or approximately 5 hours per respondent. The Commission estimates that the total annual internal cost of compliance for the 25,844 hours is approximately \$12,452,349, or approximately \$2,401 per respondent, annually.

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 website: 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 Candace Kenner, 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 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15380 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-83634; File No. SR-IEX-2018-15]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Discontinue the Router Basic Routing Option

July 13, 2018.

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 July 10, 2018, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II and III 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

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 ("Act"),4 and Rule 19b-4 thereunder,⁵ Investors Exchange LLC ("IEX" or "Exchange") is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend Rule 11.230(c) (Routing Options) to discontinue the Router Basic routing option and delete references thereto. The Exchange has designated this rule change as "non-controversial" under Section 19(b)(3)(A) of the Act 6 and provided the Commission with the notice required by Rule 19b-4(f)(6) thereunder.7

The text of the proposed rule change is available at the Exchange's website at www.iextrading.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 these statement may be examined at the places specified in Item IV below. The self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend Rule 11.230(c) (Routing Options) to delete references to the Router Basic routing option. The Exchange currently offers two routing options—Router and Router Basic—which may be elected by a User upon entry of an order eligible for routing to the Exchange.⁸ The Exchange proposes to discontinue the Router Basic option.

Rule 11.230(c)(1) describes the Exchange's Router Basic routing option under which the System 9 sends routable orders to market centers on the Exchange's proprietary System routing table. 10 If shares remain unexecuted after routing, they are posted on the Order Book or canceled, as per User instructions. Once posted to the Order Book, the unexecuted portion of such an order is eligible for the re-sweep behavior described in Rule 11.230(c)(3), market conditions permitting.

Furthermore, Rule 11.230(c)(2) describes the Exchange's Router routing option under which the System sends routable orders to the Order Book to check for available shares and then any remainder is sent to market centers on the Exchange's proprietary System routing table. If shares remain unexecuted after routing, they are

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

^{3 17} CFR 240.19b-4.

^{4 15} U.S.C. 78s(b)(1).

⁵ 17 CFR 240.19b–4.

^{6 15} U.S.C. 78s(b)(3)(A).

^{7 17} CFR 240.19b–4.

⁸ See standard FIX tag 18 (ExecInst) in the Investors Exchange FIX Specification, available on the Exchange's public website.

⁹ See Rule 1.160(nn).

¹⁰ See Rule 11.230(c). The term "System routing table" refers to the proprietary process for determining the specific trading venues, including the Order Book, to which the System routes orders and the order in which it routes them. The Exchange reserves the right to maintain a different System routing table for different routing options and to modify the System routing table at any time without notice.

posted on the Order Book or canceled, as per User instructions. Once posted to the Order Book, the unexecuted portion of such an order is eligible for the resweep behavior described in Rule 11.230(c)(3), market conditions permitting.

The Exchange evaluates its product and service offerings on an ongoing basis to identify opportunities for enhancement and simplification. After several internal analyses, the Exchange has identified that relatively fewer Users elect Router Basic in comparison to the Exchange's Router option. 11 Accordingly, the Exchange has determined to simplify the routing options offered by the Exchange by discontinuing the Router Basic option, considering the current demand for Router Basic does not warrant the infrastructure and ongoing maintenance expenses required to support the product. Users seeking to route orders to market centers on the System routing table via the Exchange will continue to be able to do so using the Router option. Furthermore, use of the Exchange's router will continue to be optional and Users may access liquidity on away market centers using alternative methods, such as connecting to those exchanges directly or through a thirdparty service provider.

In conjunction with the proposed discontinuation of Router Basic, the Exchange proposes to reserve paragraph (1) of Rule 11.230(c). The Exchange intends to implement the proposed rule change on the operative date of this filing.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with Section 6(b) of the Act in general, 12 and further the objectives of Section 6(b)(5) of the Act, 13 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, 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.

As discussed in the Purpose section, the proposed rule change is designed to simplify the Exchange's routing options, which the Exchange believes is

consistent with the protection of investors and the public interest. Furthermore, the Exchange believes the proposed changes are consistent with the protection of investors and the public interest in that, as described above, the Exchange has relatively few Users electing Router Basic. Accordingly, the Exchange has determined to simplify the routing options offered by the Exchange by discontinuing the Router Basic option, considering the current demand for Router Basic does not warrant the infrastructure and ongoing maintenance expenses required to support the product. Routing through the Exchange is voluntary, and an alternative routing option offered by the Exchange as well as other methods remain available to Users that wish to route to market centers on the System routing table. In addition, the Router Basic routing option is not a core product offering of the Exchange, nor is the Exchange required by the Act to offer such product. Therefore, the Exchange believes the proposed rule change would simplify the Exchange's routing options, and make its rules clearer and less confusing for investors by removing a routing option that will no longer be offered by the Exchange, thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, and, in general, protecting investors and the public interest. Lastly, the Exchange does not believe that this proposal will permit unfair discrimination among customers, brokers, or dealers because the Router Basic routing option will no longer be available to any Users of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposal will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not designed to address any competitive issues but rather simplify the Exchange's routing options, and eliminate the infrastructure and ongoing maintenance expenses to support a product that Members use relatively less.

Furthermore, the Exchange believes the proposed rule change does not impose any burden on intra-market competition not necessary or appropriate in furtherance of the purposes of the Act because, as described above, the Router Basic routing option will no longer be available to any Users of the Exchange, and thus all Users will be impacted in

the same manner. Further, Users seeking to route orders to market centers on the System routing table will continue to be able to do so using the Router option or may access liquidity on away market centers using alternative methods, such as connecting to those exchanges directly or through a third-party service provider.

The Exchange also does not believe that the proposed rule change would impose a burden on inter-market competition since other exchanges are free to adopt comparable routing options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A) ¹⁴ of the Act and Rule 19b–4(f)(6) ¹⁵ thereunder. 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, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.

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. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) ¹⁶ of the Act to determine whether the proposed rule change 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:

¹¹For example, during the first quarter of 2018, over two thirds of routable orders entered on the Exchange were entered under the Router option, instead of Router Basic.

^{12 15} U.S.C. 78f.

¹³ 15 U.S.C. 78f(b)(5).

^{14 15} U.S.C. 78s(b)(3)(A).

^{15 17} CFR 240.19b-4(f)(6).

^{16 15} U.S.C. 78s(b)(2)(B).

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-IEX-2018-15 on the subject line.

Paper Comments

 Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to File Number SR-IEX-2018-15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (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 website 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 this filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-IEX-2018-15 and should be submitted on or before August 9, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.17

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15369 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review: **Comment Request**

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services. 100 F Street NE, Washington, DC 20549-2736

Extension:

Rule 12d2-1, SEC File No. 270-098, OMB Control No. 3235-0081

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (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 previously approved collection of information provided for in Rule 12d2-1 (17 CFR 240.12d2-1), under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) ("Act").

On February 12, 1935, the Commission adopted Rule 12d2-11 ("Suspension of Trading") which sets forth the conditions and procedures under which a security may be suspended from trading under Section 12(d) of the Act.² Rule 12d2–1 provides the procedures by which a national securities exchange may suspend from trading a security that is listed and registered on the exchange. Under Rule 12d2–1, an exchange is permitted to suspend from trading a listed security in accordance with its rules, and must promptly notify the Commission of any such suspension, along with the effective date and the reasons for the suspension.

Any such suspension may be continued until such time as the Commission may determine that the suspension is designed to evade the provisions of Section 12(d) of the Act and Rule 12d2-2 thereunder.3 During the continuance of such suspension under Rule 12d2-1, the exchange is required to notify the Commission promptly of any change in the reasons for the suspension. Upon the restoration to trading of any security suspended under Rule 12d2-1, the exchange must notify the Commission promptly of the effective date of such restoration.

The trading suspension notices serve a number of purposes. First, they inform the Commission that an exchange has suspended from trading a listed security or reintroduced trading in a previously suspended security. They also provide the Commission with information necessary for it to determine that the suspension has been accomplished in accordance with the rules of the exchange, and to verify that the exchange has not evaded the requirements of Section 12(d) of the Act and Rule 12d2-2 thereunder by improperly employing a trading suspension. Without Rule 12d2-1, the Commission would be unable to fully implement these statutory responsibilities.

There are 21 national securities exchanges 4 that are subject to Rule 12d2–1. The burden of complying with Rule 12d2-1 is not evenly distributed among the exchanges, however, since there are many more securities listed on the New York Stock Exchange, Inc., the NASDAQ Stock Exchange, and the NYSE American LLC than on the other exchanges.⁵ There are approximately 964 responses ⁶ under Rule 12d2–1 for the purpose of suspension of trading from the national securities exchanges each year, and the resultant aggregate annual reporting hour burden would be, assuming on average one-half reporting hour per response, 482 annual burden hours for all exchanges. The related internal compliance costs associated with these burden hours are \$103,871 per year.

The collection of information obligations imposed by Rule 12d2-1 is mandatory. The response will be available to the public and will not be kept confidential.

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 website: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the

^{17 17} CFR 200.30-3(a)(12).

¹ See Securities Exchange Act Release No. 98 (February 12, 1935).

² See Securities Exchange Act Release No. 7011 (February 5, 1963), 28 FR 1506 (February 16, 1963).

³ Rule 12d2–2 prescribes the circumstances under which a security may be delisted from an exchange and withdrawn from registration under Section 12(b) of the Act, and provides the procedures for taking such action.

⁴ The Exchanges are BOX Options Exchange LLC, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe EDGA Exchange, Inc., Choe EDGX Exchange, Inc., Choe Exchange, Inc. Chicago Stock Exchange, Inc., Investors Exchange LLC, Miami International Securities Exchange, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The Nasdaq Stock Market, New York Stock Exchange LLC, NYSE Arca, Inc., NYSE American LLC, NYSE National, Inc.

 $^{^{5}}$ In fact, some exchanges do not file any trading suspension reports in a given year.

⁶ The 964 figure was calculated by averaging the numbers for compliance in 2016 and 2017, which are 1,002 and 925, respectively.

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 Candace Kenner, 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 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15377 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rules 17Ad–6 and 17Ad–7, SEC File No. 270–151, OMB Control No. 3235–0291

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 rules: Rule 17Ad–6 (17 CFR 240.17Ad–6) and Rule 17Ad–7 (17 CFR 240.17Ad–7) under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.) ("Exchange Act").

Rule 17Ad-6 under the Exchange Act requires every registered transfer agent to make and keep current records about a variety of information, such as: (1) Specific operational data regarding the time taken to perform transfer agent activities (to ensure compliance with the minimum performance standards in Rule 17Ad-2 (17 CFR 240.17Ad-2)); (2) written inquiries and requests by shareholders and broker-dealers and response time thereto; (3) resolutions, contracts, or other supporting documents concerning the appointment or termination of the transfer agent; (4) stop orders or notices of adverse claims to the securities; and (5) all canceled registered securities certificates.

Rule 17Ad–7 under the Exchange Act requires each registered transfer agent to retain the records specified in Rule 17Ad–6 in an easily accessible place for a period of six months to six years, depending on the type of record or document. Rule 17Ad–7 also specifies the manner in which records may be maintained using electronic, microfilm, and microfiche storage methods.

These recordkeeping requirements are designed to ensure that all registered transfer agents are maintaining the records necessary for transfer agents to monitor and keep control over their own performance and for the Commission to adequately examine registered transfer agents on an historical basis for compliance with applicable rules.

The Commission estimates that approximately 382 registered transfer agents will spend a total of 191,000 hours per year complying with Rules 17Ad–6 and 17Ad–7 (500 hours per year per transfer agent).

The retention period under Rule 17Ad–7 for the recordkeeping requirements under Rule 17Ad–6 is six months to six years, depending on the particular record or document. The recordkeeping and retention requirements under Rules 17Ad–6 and 17Ad–7 are mandatory to assist the Commission and other regulatory agencies with monitoring transfer agents and ensuring compliance with the rules. These rules do not involve the collection of confidential information.

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 website: 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 Candace Kenner, 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 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–15373 Filed 7–18–18; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Regulation R, Rule 701, SEC File No. 270–562, OMB Control No. 3235–0624

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 et seq.), the Securities and Exchange Commission ("Commission") is soliciting comments on the existing collection of information provided for in Regulation R, Rule 701 (17 CFR 247.701) under the Securities Exchange Act of 1934 (15 U.S.C. 78a et seq.). The Commission plans to submit this existing collection of information to the Office of Management and Budget ("OMB") for extension and approval.

Regulation R, Rule 701 requires a broker or dealer (as part of a written agreement between the bank and the broker or dealer) to notify the bank if the broker or dealer makes certain determinations regarding the financial status of the customer, a bank employee's statutory disqualification status, and compliance with suitability or sophistication standards.

The Commission estimates that brokers or dealers would, on average, notify 1,000 banks approximately two times annually about a determination regarding a customer's high net worth or institutional status or suitability or sophistication standing as well as a bank employee's statutory disqualification status. Based on these estimates, the Commission anticipates that Regulation R, Rule 701 would result in brokers or dealers making approximately 2,000 notifications to banks per year. The Commission further estimates (based on the level of difficulty and complexity of the applicable activities) that a broker or dealer would spend approximately 15 minutes per notice to a bank. Therefore, the estimated total annual third party disclosure burden for the requirements in Regulation R, Rule 701 is 500 1 hours for brokers or dealers.

Written comments are invited on: (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;

^{1 (2000} notices × 15 minutes) = 30,000 minutes/60 minutes = 500 hours.

(b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Candace Kenner, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 13, 2018.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018-15379 Filed 7-18-18; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF STATE

[Public Notice: 10468]

Notice of Determinations; Culturally Significant Object Imported for Exhibition—Determinations: "Titian's Lady in White: A Renaissance Portrait Revealed" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that a certain object to be included in the exhibition "Titian's Lady in White: A Renaissance Portrait Revealed," imported from abroad for temporary exhibition within the United States, is of cultural significance. The object is imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit object at the Columbus Museum of Art, Columbus, Ohio, from on or about August 30, 2018, until on or about December 9, 2018, 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: Julie Simpson, Attorney-Adviser, 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.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made 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 Delegation of Authority No. 236–10 of July 6, 2018.

Jennifer Z. Galt,

Principal Deputy Assistant, Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–15409 Filed 7–18–18; 8:45 am]

BILLING CODE 4710-05-P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36205]

Atlantic and Western Railway, Limited Partnership—Acquisition and Operation Exemption—CSX Transportation, Inc.

Atlantic and Western Railway, Limited Partnership (ATW), a Class III rail carrier, has filed a verified notice of exemption under 49 CFR 1150.41 to acquire and operate approximately 0.37 miles of rail line owned by CSX Transportation, Inc. (CSXT) between milepost S 198.55 and milepost S 198.92, in Sanford, N.C. (the Line).

ATW states that it entered into a Purchase and Sale Agreement with CSXT dated January 2, 2018, to acquire the Line in order to align operations and ownership of tracks in this area where ATW and CSXT operations converge. ATW also states that the proposed acquisition and operation of the Line does not impose or include an interchange commitment.

ATW certifies that the proposed transaction will not result in ATW becoming a Class II or Class I rail carrier and that the projected annual revenue of ATW will not exceed \$5 million.

The transaction may be consummated on or after August 2, 2018 (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than July 26, 2018 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. 36205, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Eric M. Hocky, Clark Hill PLC, One Commerce Square, 2005 Market Street, Suite 1000, Philadelphia, PA 19103.

According to ATW, this action is excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available on our website at *WWW.STB.GOV*.

Decided: July 13, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018-15361 Filed 7-18-18; 8:45 am]

BILLING CODE 4915-01-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, U.S. Coast Guard, and U.S. Army Corps of Engineers.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, the State Route 1 (SR 1) Lagunitas Creek Bridge Project from post miles 28.4 to 28.6 on SR 1 in the County of Marin, 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(*I*)(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 17, 2018. If the Federal law that authorizes judicial review of a

¹ ATW states that it is also acquiring certain additional excepted tracks that are not subject to the Board's jurisdiction.

claim provides a time period of less than 150 days for filing such claim, then that shorter time period applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Eric DeNardo, Environmental Branch Chief, 111 Grand Avenue MS 8B, Oakland, CA 94612, 510-286-5645 (Voice), email eric.denardo@dot.ca.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 has taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The State Route 1 (SR 1) Lagunitas Creek Bridge Project would replace the bridge over Lagunitas Creek on SR 1 in Marin County to provide a safe, seismically stable crossing of Lagunitas Creek on SR 1. The project area is in Marin County, California near the unincorporated town of Point Reyes Station. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the project, approved on June 29th, 2018. The EA, FONSI, and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at http:// www.dot.ca.gov/d4/lagunitas creekbridge/.

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. National Environmental Policy Act (NEPA)
- 2. Fixing America's Surface
 Transportation Act (Fast Act)
- 3. Clean Air Act
- 4. Federal-Aid Highway Act
- 5. Clean Water Act
- 6. Historic Sites Act
- 7. Section 106 of the National Historic Preservation Act
- 8. Archeological Resources Protection
- 9. Archeological and Historic Preservation Act
- 10. Antiquities Act
- 11. Endangered Species Act
- 12. Migratory Bird Treaty Act
- 13. Fish and Wildlife Coordination Act
- 14. Magnuson-Stevens Fishery
 Conservation and Management Act
- 15. Section 4(f) of the Department of Transportation Act

- 16. Civil Rights Act, Title VI
- 17. Farmland Protection Policy Act
- 18. Uniform Relocation Assistance and Real Property Acquisition Policies Act
- 19. Rehabilitation Act
- 20. Americans with Disabilities Act
- 21. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- 22. Resource Conservation and Recovery Act (RCRA)
- 23. Safe Drinking Water Act
- 24. Occupational Safety and Health Act
- 25. Atomic Energy Act
- 26. Toxic Substances Control Act
- 27. Federal Insecticide, Fungicide and Rodenticide Act
- 28. E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management
- 29. E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations
- 30. E.O. 12088, Federal Compliance with Pollution Control Standards

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Tashia Clemons,

Director, Planning and Environment, Federal Highway Administration, Sacramento, California.

[FR Doc. 2018–15417 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA-2018-0037]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for

comments.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under SUPPLEMENTARY INFORMATION. We are required to publish this notice in the Federal Register by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by September 17, 2018.

ADDRESSES: You may submit comments identified by DOT Docket ID Number

2018–0037 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to http://www.regulations.gov. Follow the online instructions for submitting comments.

Fax: 1-202-493-2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S.
Department of Transportation, West
Building Ground Floor, Room W12–140,
1200 New Jersey Avenue SE,
Washington, DC 20590, between 9 a.m.
and 5 p.m. ET, Monday through Friday,
except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Peter Clark, 202–366–2025, or Arnold Feldman, 202–366–2028, Office of Real Estate Services, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Annual State Right-of-way Acquisition Data.

Background: Moving Ahead for Progress in the 21st Century (MAP–21) Section 1521 (d) amends the Uniform Relocation Assistance and Real Properties Acquisition Policy Act of 1970 Section 213 (b), codified in 42 U.S.C. 4633 by requiring "that each Federal agency that has programs or projects requiring the acquisition of real property or causing a displacement from real property subject to the provisions of this Act shall provide to the lead agency an annual summary report that describes the activities conducted by the Federal agency."

Respondents: Each of the 52 state DOT's will be asked to send an annual report to the division office which outlines state-specific acquisition data.

Frequency: Annually. Every October FHWA Office of Real Estate, HQ will request this data.

Estimated Average Burden per Response: Approximately 5 hours per response.

Ēstimated Total Annual Burden Hours: Approximately 260 hours total for all 52 states.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated

burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: July 13, 2018.

Michael Howell,

 $In formation\ Collection\ Of ficer.$

[FR Doc. 2018-15426 Filed 7-18-18; 8:45 am]

BILLING CODE 4910-22-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.

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to a proposed highway project, U.S. 101 between post miles 8.2 and 8.7 in the County of Del Norte, 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 17, 2018. 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:

Kellie Eldridge, Environmental Planner, Caltrans, 1656 Union Street, Eureka, CA 95501, kellie.eldridge@dot.ca.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 has

taken final agency actions subject to 23 U.S.C. 139(l)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: The Hunter and Panther Creek Bridges Seismic Restoration Project located on U.S. 101 between post miles 8.2 and 8.7 in Del Norte County, State of California, would upgrade Hunter and Panther Creek Bridges to current seismic and design standards by (1) replacing the existing three-span structure with two pier walls at Hunter Creek with a two-span structure with one pier, and (2) by replacing the existing three-span structure with two multi-columned piers at Panther Creek with a singlespan, steel tied arch structure without piers. The project is expected to be completed within two years. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the project, approved July 5, 2018, and in other documents in the Caltrans project records. The EA, FONSI, and other project records are available by contacting Caltrans at the address provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at http://www.dot.ca.gov/dist1/d1projects/ hunter panther/.

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. National Environmental Policy Act (NEPA)
- 2. Clean Water Act
- 3. Endangered Species Act
- 4. Migratory Bird Treaty Act
- 5. Magnuson-Stevens Fishery Conservation and Management Act
- 6. Civil Rights Act, Title VI
- 7. E.O. 11990 Protection of Wetlands
- 8. E.O. 11988 Floodplain Management

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Tashia J. Clemons,

Director, Planning and Environment, Federal Highway Administration, Sacramento, California.

[FR Doc. 2018–15419 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-RY-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

Sunshine Act Meetings; Unified Carrier Registration Plan Board of Directors

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of Unified Carrier Registration Plan Board of Directors (UCR Board) and Subcommittee Meetings.

TIME AND DATE: The meetings will occur on the following schedule and will take place in the Mountain (Daylight) Time Zone:

Thursday, August 23, 2018

8:15 a.m.–9:00 a.m. Registration System Subcommittee 9:00 a.m.–12:00 Noon. UCR Board

PLACE: These meetings will be open to the public at the Radisson Hotel Salt Lake City Downtown, 215 West South Temple, Salt Lake City, UT 84101, and via conference call. Those not attending the meetings in person may call toll-free; 1–877–422–1931, passcode 2855443940, to listen and participate in the meetings.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED: The Unified Carrier Registration Plan Board of Directors (the Board) will continue its work in developing and implementing the Unified Carrier Registration Plan and Agreement and to that end, may consider matters properly before the Board. An agenda for these meetings will be available no later than 5:00 p.m. Eastern Daylight Time, August 14, 2018 at: https://ucrplan.org.

FOR FURTHER INFORMATION CONTACT: Mr. Avelino Gutierrez, Chair, Unified Carrier Registration Board of Directors at (505) 827–4565.

Issued on: July 16, 2018.

Larry W. Minor,

Associate Administrator, Office of Policy, Federal Motor Carrier Safety Administration. [FR Doc. 2018–15603 Filed 7–17–18; 4:15 pm]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Notice of Funding Opportunity for Consolidated Rail Infrastructure and Safety Improvements

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT). **ACTION:** Notice of Funding Opportunity (NOFO or notice).

SUMMARY: This notice details the application requirements and procedures to obtain grant 1 funding for eligible projects under the Consolidated Rail Infrastructure and Safety Improvements (CRISI) Program. CRISI Program funding under this notice is provided by the Consolidated Appropriations Act, 2018, (2018) Appropriation). Funding for positive train control (PTC) systems deployment included in the 2018 Appropriation is provided under a different NOFO published on May 18, 2018 (CRISI PTC NOFO). Applicants may apply for funding for PTC system elements under this NOFO as well if such elements are otherwise eligible under the CRISI Program. The opportunities described in this notice are made available under Catalog of Federal Domestic Assistance (CFDA) number 20.325, "Consolidated Rail Infrastructure and Safety Improvements.'

DATES: Applications for funding under this solicitation are due no later than 5:00 p.m. EDT, September 17, 2018. Applications received after 5:00 p.m. EDT on September 17, 2018 will not be considered for funding. Incomplete applications will not be considered for funding. See Section D of this notice for additional information on the application process.

ADDRESSES: Applications must be submitted via www.Grants.gov. Only applicants who comply with all submission requirements described in this notice and submit applications through www.Grants.gov will be eligible for award. For any supporting application materials that an applicant is unable to submit via www.Grants.gov (such as oversized engineering drawings), an applicant may submit an original and two (2) copies to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36-412, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, applicants are advised to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline.

FOR FURTHER INFORMATION CONTACT: For further project or program-related information in this notice, please contact Ms. Frances Bourne, Office of

Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–207 Washington, DC 20590; email: frances.bourne@dot.gov; phone: 202-493-6366. Grant application submission and processing questions should be addressed to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36-412, Washington, DC 20590; email: amy.houser@dot.gov; phone: 202-493-0303.

SUPPLEMENTARY INFORMATION:

Notice to applicants: FRA recommends that applicants read this notice in its entirety prior to preparing application materials. A list providing the definitions of key terms used throughout the NOFO is in Section A(2) below. These key terms are capitalized throughout the NOFO. There are several administrative prerequisites and specific eligibility requirements described herein that applicants must comply with to submit an application. Additionally, applicants should note that the required Project Narrative component of the application package may not exceed 25 pages in length.

Table of Contents

- A. Program Description
- B. Federal Award Information
- C. Eligibility Information
- D. Application and Submission Information
- E. Application Review Information
- F. Federal Award Administration Information
- G. Federal Awarding Agency Contacts

A. Program Description

1. Overview

This program provides a comprehensive solution to leverage private, state and local investments to support safety enhancements and general improvements to infrastructure for both intercity passenger and freight railroads. The U.S. rail network is central to the success of the American economy, carrying more than 1.6 billion tons of freight valued at nearly \$600 billion annually, and over 31.3 million passengers on intercity rail passenger transportation services. Both services primarily operate over privately-owned and maintained infrastructure, allowing for strong private, capital market investment that generates public benefit, including public-private partnerships among other models.

The Department is committed to addressing the unmet transportation infrastructure needs of rural areas. Underinvestment in rural transportation systems has allowed a slow and steady decline in the transportation routes that

connect rural American communities to each other and to the rest of the country, fraying the fabric of American interconnectivity. A majority of the nation's rail route miles are in rural America. Investment is necessary to grow rural economies, facilitate freight movement, improve access to reliable and affordable transportation options and enhance health access and safety for residents.

The Department also recognizes the importance of applying life cycle asset management principles throughout America's infrastructure. It is important for rail infrastructure owners and operators, as well as those who may apply on their behalf, to plan for the maintenance and replacement of assets and the associated costs. In light of recent fatal passenger rail accidents, the Department particularly recognizes the opportunity to enhance safety in both track and equipment through this grant program.

Congress authorized this grant program for the Secretary to invest in a wide range of projects within the United States to improve railroad safety, efficiency, and reliability; mitigate congestion at both intercity passenger and freight rail chokepoints; enhance multi-modal connections; and lead to new or substantially improved Intercity Passenger Rail Transportation corridors. Additionally, the program includes rail safety projects, such as grade crossing enhancements, and rail line relocations and improvements. Applicable work also includes: rail regional and corridor planning, environmental analyses, and research, workforce development, and training. The purpose of this notice is to solicit applications for the competitive CRISI Program funding provided in the 2018 Appropriation that was not included in the CRISI PTC NOFO. The CRISI Program is authorized under Section 11301 of the Fixing America's Surface Transportation (FAST) Act, Public Law 114-94 (2015); 49 U.S.C. 24407 and funds made available in this NOFO are provided in the 2018 Appropriation.

2. Definitions of Key Terms

a. "Benefit-Cost Analysis" (or "Cost-Benefit Analysis") is a systematic, data driven, and transparent analysis comparing monetized project benefits and costs, using a no-build baseline and properly discounted present values, including concise documentation of the assumptions and methodology used to produce the analysis; a description of the baseline, data sources used to project outcomes, and values of key input parameters; basis of modeling including spreadsheets, technical

¹The term "grant" is used throughout this document and is intended to reference funding awarded through a grant agreement, as well as funding awarded through a cooperative agreement.

memos, etc.; and presentation of the calculations in sufficient detail and transparency to allow the analysis to be reproduced and for sensitivity of results evaluated by FRA. Please refer to the Benefit-Cost Analysis Guidance for Discretionary Grant Programs prior to preparing a BCA at https:// www.transportation.gov/office-policy/ transportation-policy/benefit-costanalysis-guidance. In addition, please also refer to the BCA FAQs on FRA's website for some rail specific examples of how to apply the BCA Guidance for Discretionary Grant Programs to CRISI applications.

b. "Capital Project" means a project for: Acquiring, constructing, improving, or inspecting rail equipment, track and track structures, or a rail facility; expenses incidental to the acquisition or Construction including pre-construction activities (such as designing, engineering, location surveying, mapping, acquiring rights-of-way) and related relocation costs, environmental studies, and all work necessary for FRA to approve the project under the National Environmental Policy Act and related environmental laws and regulations; highway-rail grade crossing improvements; communication and

facilities.
c. "Construction" means the production of fixed works and structures or substantial alterations to such structures or land and associated costs.

signalization improvements; and

rehabilitating, remanufacturing or

overhauling rail rolling stock and

d. "Final Design (FD)" means design activities following Preliminary Engineering, and at a minimum, includes the preparation of final Construction plans, detailed specifications, and estimates sufficiently detailed to inform project stakeholders (designers, reviewers, contractors, suppliers, etc.) of the actions required to advance the project from design through completion of Construction.

e. "Improvement" means repair or enhancement to existing Rail Infrastructure, or Construction of new Rail Infrastructure, that results in efficiency of the rail system and the safety of those affected by the system.

f. "Initiation" or "Initiate" means commencing service on a route that did not previously operate Intercity Rail Passenger Transportation.

g. "Intercity Rail Passenger Transportation" means rail passenger transportation, except commuter rail passenger transportation. See 49 U.S.C. 24401(3). In this notice, "Intercity Passenger Rail Service" and "Intercity Passenger Rail Transportation" are equivalent terms to "Intercity Rail Passenger Transportation."

h. "National Environmental Policy Act (NEPA)" is a Federal law that requires Federal agencies to assess the environmental impacts of a proposed action in consultation with appropriate federal, state, and local authorities, and with the public. The NEPA class of action depends on the nature of the proposed action, its complexity, and the potential impacts. For purposes of this NOFO, NEPA also includes all related Federal laws and regulations including Section 4(f) of the Department of Transportation Act, Section 7 of the Endangered Species Act, and Section 106 of the National Historic Preservation Act. (See FRA's Environmental Procedures at: https:// www.fra.dot.gov/eLib/details/L02561.)

i. "Planning" means activities that support the development of a state or regional rail plan or a corridor service development plan.

j. "Positive Train Control (PTC) system" is defined by 49 CFR 270.5 to mean a system designed to prevent train-to-train collisions, overspeed derailments, incursions into established work zone limits, and the movement of a train through a switch left in the wrong position, as described in 49 CFR part 236, subpart I.

k. "Preliminary Engineering (PE)" means engineering design to: (1) Define a project, including identification of all environmental impacts, design of all critical project elements at a level sufficient to assure reliable cost estimates and schedules, (2) complete project management and financial plans, and (3) identify procurement requirements and strategies. The PE development process starts with specific project design alternatives that allow for the assessment of a range of rail improvements, specific alignments, and project designs—to be used concurrent with project or service level NEPA and related analyses. PE occurs prior to FD and Construction.

l. "Rail Carrier" means a person providing common carrier railroad transportation for compensation, but does not include street, suburban, or interurban electric railways not operated as part of the general system of rail transportation. See 49 U.S.C. 10102(5).

m. "Railroad Infrastructure" means intermodal or rail facilities, including track, bridges, tunnels, rail yards, buildings, passenger stations, and maintenance and repair shops. In this NOFO, "Rail Infrastructure" is an equivalent term to "Railroad Infrastructure."

- n. "Relocation" is defined by 49 CFR 262.3 to mean moving a rail line vertically or laterally to a new location. Vertical Relocation refers to raising above the current ground level or sinking below the current ground level of a rail line. Lateral Relocation refers to moving a rail line horizontally to a new location.
- o. "Restoration" means reinstating service to a route that formerly operated Intercity Rail Passenger Transportation.
- p. "Rural Project" means a project in which all or the majority of the project (determined by the geographic location or locations where the majority of the project funds will be spent) is located in a Rural Area.
- q. "Rural Area" is defined in 49 U.S.C. 24407(g)(2) to mean any area not in an urbanized area as defined by the Census Bureau. The Census Bureau defines Urbanized Area (UA) as an area with a population of 50,000 or more people. Updated lists of UAs as defined by the Census Bureau are available on the Census Bureau website at http://www2.census.gov/geo/maps/dc10map/UAUC RefMap/ua/.

r. "Tier 1 NEPA" includes the analysis and evaluation of the potential environmental impacts of an action at a broad level, such as a program concept for an entire corridor, and typically does not lead directly to project construction. It identifies the potential environmental impacts of the alternatives being considered for the program, as well as the mitigations that may be needed to address the impacts. The potential environmental impacts and mitigations must be incorporated into each alternative that is evaluated. These are generally Environmental Impact Statements (EISs) that result in the

identification of a preferred alternative. s. "Tier 2 NEPA" includes the required analysis and evaluation of the potential environmental impacts of an action at a project-specific level of detail. Tier 2 NEPA should be sufficient to support Final Design and Construction activities and may include an EIS, an environmental assessment (EA), or a categorical exclusion (CE).

B. Federal Award Information

1. Available Award Amount

The total funding available for awards under this NOFO is \$318,430,337 of which \$35,547,000 will be for projects under 49 U.S.C. 24407(c)(2) that contribute to the Initiation or Restoration of Intercity Passenger Rail Service consistent with the 2018

¹ See 74 FR 53030, 53043 (August 24, 2011) available at https://www2.census.gov/geo/pdfs/ reference/fedreg/fedregv76n164.pdf.

Appropriation. Of the CRISI funding made available in the 2018 Appropriation (including amounts available under this NOFO and the CRISI PTC NOFO) at least 25 percent, will be made available for Rural Projects as authorized under 49 U.S.C. 24407(g).

After \$5,925,470 is set aside for FRA award and program oversight, the balance of the 2018 Appropriation CRISI Program funding includes \$250,000,000 set aside for certain PTC projects and \$18,191,193 set aside for Special Transportation Circumstances. These funds were announced under separate NOFOs.

2. Award Size

There are no predetermined minimum or maximum dollar thresholds for awards. FRA anticipates making multiple awards with the available funding. FRA may not be able to award grants to all eligible applications, nor even to all applications that meet or exceed the stated evaluation criteria (see Section E, Application Review Information). Projects may require more funding than is available. FRA encourages applicants to propose projects or components of projects that have operational independence and that can be completed and implemented with CRISI funding as a piece of the total project cost together with other, non-federal sources.

FRA strongly encourages applicants to identify and include other state, local, public, or private funding or financing to support the proposed project in order to maximize competitiveness.

3. Award Type

FRA will make awards for projects selected under this notice through grant agreements and/or cooperative agreements. Grant agreements are used when FRA does not expect to have substantial Federal involvement in carrying out the funded activity. Cooperative agreements allow for substantial Federal involvement in carrying out the agreed upon investment, including technical assistance, review of interim work products, and increased program oversight. The funding provided under these cooperative agreements will be made available to grantees on a reimbursable basis. Applicants must certify that their expenditures are allowable, allocable, reasonable, and necessary to the approved project before seeking reimbursement from FRA. Additionally, the grantee is expected to expend matching funds at the required percentage alongside Federal funds throughout the life of the project. See an example of standard terms and

conditions for FRA grant awards at: https://www.fra.dot.gov/eLib/Details/L19057.

4. Concurrent Applications

As DOT and FRA are concurrently soliciting applications for transportation infrastructure projects for several financial assistance programs, applicants may submit applications requesting funding for a particular project to one or more of these programs. In the application for CRISI Program funding under this NOFO, applicants must indicate the other programs, and if applicable the other CRISI NOFOs, to which they submitted or plan to submit an application for funding the entire project or certain project components, as well as highlight new or revised information in the application responsive to this NOFO that differs from the application(s) for other federal financial assistance programs or other CRISI NOFOs.

C. Eligibility Information

This section of the notice explains applicant eligibility, cost sharing and matching requirements, project eligibility, and project component operational independence. Applications that do not meet the requirements in this section will be ineligible for funding. Instructions for submitting eligibility information to FRA are detailed in Section D of this NOFO.

1. Eligible Applicants

The following entities are eligible applicants for all project types permitted under this notice:

- a. A State;
- b. A group of States;
- c. An Interstate Compact;
- d. A public agency or publicly chartered authority established by one or more States; ²
 - e. A political subdivision of a State;
- f. Amtrak or another Rail Carrier that provides Intercity Rail Passenger Transportation (as defined in 49 U.S.C. 24102);
- g. A Class II railroad or Class III railroad (as those terms are defined in 49 U.S.C. 20102);
- h. Any Rail Carrier or rail equipment manufacturer in partnership with at least one of the entities described in paragraph (a) through (e); ³
- i. The Transportation Research Board together with any entity with which it contracts in the development of rail-

related research, including cooperative research programs;

- j. A University transportation center engaged in rail-related research; or
- k. A non-profit labor organization representing a class or craft of employees of Rail Carriers or Rail Carrier contractors.

Applications must identify an eligible applicant as the lead applicant. The lead applicant serves as the primary point of contact for the application, and if selected, as the recipient of the CRISI Program grant award. Eligible applicants may reference entities that are not eligible applicants in an application as a project partner.

2. Cost Sharing or Matching

The Federal share of total costs for projects funded under this notice will not exceed 80 percent, though FRA will provide selection preference to applications where the proposed Federal share of total project costs is 50 percent or less. The estimated total cost of a project must be based on the best available information, including engineering studies, studies of economic feasibility, environmental analyses, and information on the expected use of equipment and/or facilities. Additionally, in preparing estimates of total project costs, applicants should refer to FRA's cost estimate guidance documentation, "Capital Cost Estimating: Guidance for Project Sponsors," which is available at: https://www.fra.dot.gov/Page/P0926.

The minimum 20 percent non-Federal match may be comprised of public sector (e.g., state or local) and/or private sector funding. FRA will not consider any Federal financial assistance, nor any non-Federal funds already expended (or otherwise encumbered) that do not comply with 2 CFR 200.458, as applicable, toward the matching requirement. FRA is limiting the first 20 percent of the non-Federal match to cash contributions only. FRA will not accept "in-kind" contributions for the first 20 percent in matching funds. Eligible in-kind contributions may be accepted for any non-Federal matching beyond the first 20 percent. In-kind contributions, including the donation of services, materials, and equipment, may be credited as a project cost, in a uniform manner consistent with 2 CFR 200.306. Moreover, FRA encourages applicants to broaden their funding table in applications. Non-federal shares consisting of funding from multiple sources (e.g., a state, county, railroad, and university contributing to a grade crossing improvement) to demonstrate broad participation and cost sharing

² See Section D(2)(a)(iv) for supporting documentation required to demonstrate eligibility under this eligibility category.

³ See Section D(2)(a)(iv) for supporting information required to demonstrate eligibility under this eligibility category.

from affected stakeholders, will be given preference.

Amtrak or another Rail Carrier may use ticket and other non-Federal revenues generated from its operations and other sources as matching funds. Applicants must identify the source(s) of its matching and other funds, and must clearly and distinctly reflect these funds as part of the total project cost.

Before applying, applicants should carefully review the principles for cost sharing or matching in 2 CFR 200.306. See Section D(2)(a)(iii) for required application information on non-Federal match and Section E for further discussion of FRA's consideration of matching funds in the review and selection process. FRA will approve preaward costs consistent with 2 CFR 200.458, as applicable. See Section D(6).

3. Other

a. Project Eligibility

The following rail projects within the United States that improve the safety, efficiency, and/or reliability of passenger and/or freight rail transportation systems are eligible for funding under 49 U.S.C. 24407 and this NOFO.

- i. Under 49 U.S.C. 24407(c)(1) deployment of non-PTC railroad safety technology and rail integrity inspection systems. Examples include: Broken rail detection and warning systems; track intrusion systems; and hot box detectors, wheel impact load detectors, and other safety improvements.⁵
- ii. A capital project as defined in 49 U.S.C. 24401(2) relating to Intercity Passenger Rail Service, except that such projects under this NOFO are not required to be in a State rail plan. Examples include: Acquisition, improvement, or rehabilitation of railroad equipment (locomotives and rolling stock); Railroad Infrastructure (grade crossings, catenary, and signals); and rail facilities (yards, passenger stations, or maintenance and repair shops).
- iii. A Capital Project necessary to address congestion challenges affecting rail service. Examples include: Projects addressing congestion that increase rail capacity; add or upgrade the condition, clearances, and capacity of rail mainlines; enhance capacity and service with less conflict between freight and intercity passenger rail; reduce delays and risks associated with highway-rail

grade crossings; and provide more effective rail equipment.

- iv. A Capital Project necessary to reduce congestion and facilitate ridership growth in Intercity Passenger Rail Transportation along heavily traveled rail corridors. Examples include: Projects addressing congestion that improve stations; increase rail capacity; reduce conflict between freight and intercity passenger rail; reduce delays and risks associated with highway-rail grade crossings; and provide more effective rail equipment.
- v. A highway-rail grade crossing improvement project, including installation, repair, or improvement of grade separations, railroad crossing signals, gates, and related technologies; highway traffic signalization; highway lighting and crossing approach signage; roadway improvements such as medians or other barriers; railroad crossing panels and surfaces; and safety engineering improvements to reduce risk in quiet zones or potential quiet zones.
- vi. A rail line Relocation and Improvement project. Examples include projects that: Improve the route or structure of a rail line by replacing degraded track; enhance/relocate railroad switching operations; add or lengthen passing tracks to increase capacity; improve interlockings; and relocate rail lines to alleviate congestion, and eliminate frequent rail service interruptions.
- vii. A Capital Project to improve short-line or regional Railroad Infrastructure.
- viii. The preparation of regional rail and corridor service development plans and corresponding environmental analyses. (See the examples under Track 1 and 2 below in Subsections C(3)(b)(i)—(ii) as they apply to regional and corridor rail Planning.)
- ix. A project necessary to enhance multimodal connections or facilitate service integration between rail service and other modes, including between Intercity Rail Passenger Transportation and intercity bus service or commercial air service. Examples include: Intermodal transportation facilities projects that encourage joint scheduling, ticketing, and/or baggage handling; freight rail intermodal connections; and rail projects improving access to ports.
- x. The development and implementation of a safety program or institute designed to improve rail safety. Examples include: Employee training; and public safety outreach and education.
- xi. Any research that the Secretary considers necessary to advance any

particular aspect of rail related capital, operations, or safety improvements.

xii. Workforce development and training activities, coordinated to the extent practicable with the existing local training programs supported by the Department of Transportation, the Department of Labor, and the Department of Education.

b. Project Tracks for Eligible Projects

Applicants are not limited in the number of projects for which they seek funding. FRA will not limit eligible projects from consideration for funding for planning, environmental, engineering, design, and construction elements of the same project in the same application. Applicants are allowed to include multiple phases of a project in the same application. However, depending on the project, applications for multiple phases of project development may not contain sufficient detail with regards to scope, schedule, or budget for all phases of the application to compete well in the application review process.4

An applicant must identify one or more of the following four tracks for an eligible project: Track 1—Planning; Track 2—PE/NEPA; Track 3—FD/ Construction; or Track 4—Research, Safety Programs and Institutes.

i. Track 1—Planning Track 1 consists of ĕligible rail Planning projects. Examples include the technical analyses and associated environmental analyses that support the development of state rail plans, regional rail plans, and corridor service development plans, including: Identification of alternatives, rail network Planning, market analysis, travel demand forecasting, revenue forecasting, railroad system design, railroad operations analysis and simulation, equipment fleet Planning, station and access analysis, conceptual engineering and capital programming, operating and maintenance cost forecasting, capital replacement and renewal analysis, railroad industry governance and organization, and economic analysis.

ii. Track 2—PE/NEPA Track 2 consists of eligible PE/NEPA projects. PE examples include: PE drawings and specifications (scale

⁵ Only FD and Construction costs are eligible within this project eligibility category. Funding for PTC projects under 49 U.S.C. 24407(c)(1) are eligible under the CRISI PTC NOFO published on May 18, 2018, and such projects are not eligible for funding under this NOFO.

⁴The scope, schedule, and budget necessary to implement a project, as well as the definition of the project's potential benefits, are typically informed by the work conducted in prior phases of project development (e.g., the specific elements of an FD/Construction project and their cost estimates are developed and refined through PE.) The evaluation criteria for the CRISI program (see Section E of this NOFO) considers the level of detail contained in the applicant's proposed scope of work and readiness for the project to be implemented.

drawings at the 30% design level, including track geometry as appropriate); design criteria, schematics and/or track charts that support the development of PE; and work that can be funded in conjunction with developing PE, such as operations modeling, surveying, project work/ management plans, preliminary cost estimates, and preliminary project schedules. NEPA examples include analysis and documentation related to a Tier 2 NEPA EIS, EA or CE. PE/NEPA projects funded under this NOFO must result in sufficiently developed product(s) to support FD or Construction activities.

iii. Track 3—FD/Construction

Track 3 consists of eligible projects consisting of FD, Construction, and project implementation and deployment activities. Applicants must complete all necessary Planning, PE and NEPA requirements for FD/Construction projects. FD funded under this track must: Resolve remaining uncertainties or risks associated with changes to design scope; address procurement processes; and update and refine plans for financing the project or program to reflect accurately the expected year-ofexpenditure costs and cash flow projections. Applicants selected for funding for FD/Construction must demonstrate the following to FRA's satisfaction:

- (A) PE is completed for the proposed project, resulting in project designs that are reasonably expected to conform to all regulatory, safety, security, and other design requirements, including those under the Americans with Disabilities Act (ADA);
- (B) NEPA is completed for the proposed project;
- (C) Signed agreements with key project partners, including infrastructure-owning entities; and
- (D) A project management plan is inplace for managing the implementation of the proposed project, including the management and mitigation of project risks.
- FD examples include: Drawings at the 100% Design Level, interim design drawings that support development (e.g., drawings at the 60% Design Level), project work/project management plan, cost estimates, project schedules, and right-of-way acquisition and relocation plans. Construction examples include: Additions, improvements, replacements, renovations and/or repairs to track, bridge, station, rail yard, signal, and communication system infrastructure, or other railroad safety technology.

iv. Track 4—Research, Safety Programs and Institutes (Non-Railroad Infrastructure)

Track 4 consists of projects not falling within Tracks 1–3 and for the development and implementation of workforce development activities, research, safety programs or institutes designed to improve rail safety that clearly demonstrate the expected positive impact on rail safety. Sufficient detail must be provided on what the project will accomplish, as well as the applicant's capability to achieve the proposed outcomes. Examples include: Initiatives for improving rail safety, training, public outreach, and education.

c. Project Component Operational Independence

If an applicant requests funding for a project that is a component or set of components of a larger project, the project component(s) must be attainable with the award amount, together with other funds as necessary, obtain operational independence, and must comply with all eligibility requirements described in Section C.

In addition, the component(s) must be capable of independent analysis and decision making, as determined by FRA, under NEPA (*i.e.*, have independent utility, connect logical termini, if applicable, and not restrict the consideration of alternatives for other reasonably foreseeable rail projects.)

d. Rural Project

FRA will consider a project to be in a Rural Area if all or the majority of the project (determined by geographic location(s) where the majority of the project funds will be spent) is located in a Rural Area. However, in the event FRA elects to fund a component of the project, then FRA will reexamine whether the project is in a Rural Area.

D. Application and Submission Information

Required documents for the application are outlined in the following paragraphs. Applicants must complete and submit all components of the application. See Section D(2) for the application checklist. FRA welcomes the submission of additional relevant supporting documentation, such as planning, engineering and design documentation, and letters of support from partnering organizations that will not count against the Project Narrative 25-page limit.

1. Address To Request Application Package

Applicants must submit all application materials in their entirety through www.Grants.gov no later than 5:00 p.m. EDT, on September 17, 2018. FRA reserves the right to modify this deadline. General information for submitting applications through Grants.gov can be found at: https://www.fra.dot.gov/Page/P0270.

For any supporting application materials that an applicant cannot submit via Grants.gov, such as oversized engineering drawings, an applicant may submit an original and two (2) copies to Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36-412, Washington, DC 20590. However, due to delays caused by enhanced screening of mail delivered via the U.S. Postal Service, FRA advises applicants to use other means of conveyance (such as courier service) to assure timely receipt of materials before the application deadline. Additionally, if documents can be obtained online, providing instructions to FRA on how to access files on a referenced website may also be sufficient.

2. Content and Form of Application Submission

FRA strongly advises applicants to read this section carefully. Applicants must submit all required information and components of the application package to be considered for funding. Additionally, applicants selected to receive funding must generally satisfy the grant readiness checklist requirements on https://www.fra.dot.gov/Page/P0268 as a precondition to FRA issuing a grant award, as well as the requirements in 49 U.S.C. 24405 explained in part at https://www.fra.dot.gov/page/P0185.

Required documents for an application package are outlined in the checklist below.

- i. Project Narrative (see D.2.a)
- ii. Statement of Work (see D.2.b.i)
- iii. Benefit-Cost Analysis (see D.2. b.ii)
- iv. SF424—Application for Federal Assistance
- v. Either: SF 424A—Budget Information for Non-Construction projects (required for Tracks 1, 2 and 4) or SF 424C—Budget Information for Construction (required for any application that includes Track 3)
- vi. Either: SF 424B—Assurances for Non-Construction projects (required for Tracks 1, 2 and 4) or SF 424D— Assurances for Construction (required

for any application that includes Track 3)

vii. FRA's Additional Assurances and Certifications

viii. SF LLL—Disclosure of Lobbying Activities

a. Project Narrative

This section describes the minimum content required in the Project Narrative of the grant application. The Project Narrative must follow the basic outline below to address the program requirements and assist evaluators in locating relevant information.

I. Cover Page See D.2.a.i.

| II. Project Summary | See D.2.a.ii. |
|-----------------------------|-----------------|
| III. Project Funding | See D.2.a.iii. |
| IV. Applicant Eligibility | See D.2.a.iv. |
| V. Project Eligibility | See D.2.a.v. |
| VI. Detailed Project De- | See D.2.a.vi. |
| scription. | |
| VII. Project Location | See D.2.a.vii. |
| VIII. Evaluation and Selec- | See D.2.a.viii. |
| tion Criteria. | |
| IX. Project Implementation | See D.2.a.ix. |
| and Management. | |
| X. Planning Readiness | See D.2.a.x. |
| XI. Environmental Readi- | See D.2.a.xi. |
| ness. | |
| | |

The above content must be provided in a narrative statement submitted by the applicant. The Project Narrative may not exceed 25 pages in length (excluding cover pages, table of contents, and supporting documentation). FRA will not review or consider for award applications with Project Narratives exceeding the 25-page limitation. If possible, applicants should submit supporting documents via website links rather than hard copies. If supporting documents are submitted, applicants must clearly identify the page number(s) of the relevant portion in the Project Narrative supporting documentation. The Project Narrative must adhere to the following outline.

i. *Cover Page:* Include a cover page that lists the following elements in a table:

1,2,3 and/or 4.

Project Title:

NEPA stage:

cost:

Federal Grant Program:

Yes/no.

Yes/no.

Yes/no (If yes, please specify in which plans the project is currently programmed).

Yes/no Percentage of total project

ii. Project Summary: Provide a brief 4–6 sentence summary of the proposed project and what the project will entail. Include challenges the proposed project aims to address, and summarize the intended outcomes and anticipated benefits that will result from the proposed project.

iii. Project Funding: Indicate in table format the amount of Federal funding requested, the proposed non-Federal match, identifying contributions from the private sector if applicable, and total project cost. Describe the non-Federal

funding arrangement, including multiple sources of non-federal funding if applicable. Include funding commitment letters outlining funding agreements, as attachments or in an appendix. Identify any specific project components that the applicant proposes for partial project funding. If all or a majority of a project is located in a Rural Area, identify the Rural Area(s) and estimated percentage of project costs that will be spent in the Rural Area. Identify any previously incurred costs, as well as other sources of Federal funds

committed to the project and any pending Federal requests. Also, note if the requested Federal funding under this or other CRISI NOFOs or other programs must be obligated or spent by a certain date due to dependencies or relationships with other Federal or non-Federal funding sources, related projects, law, or other factors. If applicable, provide the type and estimated value of any proposed in-kind contributions, and demonstrate how the in-kind contributions meet the requirements in 2 CFR 200.306.

Example Project Funding Table:

| Task # | Task Name/Project Component | Cost | Percentage of Total Cost |
|--|-----------------------------------|-------------------|-----------------------------|
| 1 | | | |
| 2 | | | |
| Total Project Cos | t | | |
| Federal Funds Received from Previous Grant | | | |
| CRISI Federal Funding Request | | | |
| Non-Federal Funding/Match | | Cash: In-Kind: | |
| Portion of Non-Federal Funding from the Private Sector | | | |
| Portion of Total Project Costs | | | |
| Spent in a Rural Area | | | |
| Pending Federal Funding Requests | | | |

- iv. Applicant Eligibility: Explain how the applicant meets the applicant eligibility criteria outlined in Section C of this notice, including references to creation or enabling legislation for public agencies and publicly chartered authorities established by one or more States. If the applicant is eligible under 49 U.S.C. 24407(b)(8) as a rail carrier or rail equipment manufacturer in partnership with at least one of the other eligible entities, the applicant should explain the partnership and each entity's contribution to the partnership.
- v. *Project Eligibility:* Identify which project eligibility category the project is eligible under in Section C(3) of this notice, and explain how the project meets the project eligibility criteria.
- vi. Detailed Project Description:
 Include a detailed project description that expands upon the brief project summary. This detailed description should provide, at a minimum, background on the challenges the project aims to address; the expected users and beneficiaries of the project, including all railroad operators; the specific components and elements of the project; and any other information the applicant deems necessary to justify the proposed project. If applicable,

explain how the project will benefit communities in Rural Areas.

For all projects, applicants must provide information about proposed performance measures, as discussed in Section F(3)(c) and required in 2 CFR 200.301 and 49 U.S.C. 24407(f).

- (A) Grade crossing information, if applicable: For any project that includes grade crossing components, cite specific DOT National Grade Crossing Inventory information, including the railroad that owns the infrastructure (or the crossing owner, if different from the railroad), the primary railroad operator, the DOT crossing inventory number, and the roadway at the crossing. Applicants can search for data to meet this requirement at the following link: http://safetydata.fra.dot.gov/OfficeofSafety/default.aspx.
- (B) Heavily traveled rail corridor information, if applicable: For any project eligible under the eligibility category in Subsection C(3)(a)(iv), that reduces congestion and facilitates ridership growth in Intercity Passenger Rail Transportation, describe how the project is located on a heavily traveled rail corridor.
- (C) *PTC information, if applicable:* For any project that includes deploying PTC systems, applicants must:

- 1. Document submission of a revised Positive Train Control Implementation Plan (PTCIP) to FRA as required by 49 U.S.C. 20157(a);
- 2. Document that it is a tenant on one or more host railroads that submitted a revised PTCIP to FRA as required by 49 U.S.C. 20157(a), which states the tenant railroad is equipping its rolling stock with a PTC system and provides all other information required under 49 CFR 236.1011 regarding the tenant railroad; or
- 3. Document why the applicant is not required to submit a revised PTCIP as required by 49 U.S.C. 20157(a), and whether the proposed project will assist in the deployment (*i.e.*, installation and/or full implementation) of a PTC system required under 49 U.S.C. 20157.
- vii. *Project Location:* Include geospatial data for the project, as well as a map of the project's location. On the map, include the Rural Area boundaries, if applicable, in which the project will take place.
- viii. Evaluation and Selection Criteria: Include a thorough discussion of how the proposed project meets all the evaluation criteria and selection criteria, as outlined in Section E of this notice. If an application does not sufficiently address the evaluation and selection

criteria, it is unlikely to be a competitive application. For the life-cycle cost selection criteria, applicants should demonstrate a credible plan to maintain their asset without having to rely on federal funding including a description of the applicants' approach to ensuring operations and maintenance will not be underfunded in future years.

ix. Project Implementation and Management: Describe proposed project implementation and project management arrangements. Include descriptions of the expected arrangements for project contracting, contract oversight, change-order management, risk management, and conformance to Federal requirements for project progress reporting (see https://www.fra.dot.gov/Page/P0274). Describe past experience in managing and overseeing similar projects.

x. Planning Readiness for Tracks 2 and 3 (PE/NEPA and FD/Construction Projects: Provide information about the planning process that analyzed the investment needs and service objectives of the project. If applicable, cite sources of this information from a Service Development Plan, State or regional rail plan, or similar planning document where the project has been identified for solving a specific existing transportation problem, and makes the case for investing in the proposed solution.

xi. Environmental Readiness for Track 3 FD/Construction Projects: If the NEPA process is complete, an applicant should indicate the date of completion, and provide a website link or other reference to the documents demonstrating compliance with NEPA, which might include a final CE, Finding of No Significant Impact, or Record of Decision. If the NEPA process is not yet underway or is underway, but is not complete, the application should detail the type of NEPA review underway, where the project is in the process, and indicate the anticipated date of completion of all NEPA and related milestones. If the last agency action with respect to NEPA documents occurred more than three years before the application date, the applicant should describe why the project has been delayed and include a proposed approach for verifying, and if necessary, updating this information in accordance with applicable NEPA requirements. Additional information regarding FRA's environmental processes and requirements are located at https:// www.fra.dot.gov/eLib/Details/L05286.

b. Additional Application Elements

Applicants must submit: i. A Statement of Work (SOW) addressing the scope, schedule, and budget for the proposed project if it were selected for award. The SOW must contain sufficient detail so FRA, and the applicant, can understand the expected outcomes of the proposed work to be performed and monitor progress toward completing project tasks and deliverables during a prospective grant's period of performance. Applicants must use FRA's standard SOW template to be considered for award. The SOW template is located at https:// www.fra.dot.gov/eLib/Details/L18661. When preparing the budget as part of the SOW, the total cost of a project must be based on the best available information as indicated in cited references that include engineering studies, studies of economic feasibility, environmental analyses, and information on the expected use of equipment or facilities.

ii. A Benefit-Cost Analysis (BCA), as an appendix to the Project Narrative for each project submitted by an applicant. The BCA must demonstrate in economic terms the merits of investing in the proposed project. The BCA for Track 2—PE/NEPA projects should be for the underlying project, not the PE/NEPA work itself. The project narrative should summarize the project's benefits.

Benefits may apply to existing and new rail users, as well as users of other modes of transportation. In some cases, benefits may be applied to populations in the general vicinity of the project area. Improvements to multimodal connections and shared-use rail corridors may benefit all users involved. Benefits may be quantified for savings in safety costs, reduced costs from disruption of service, maintenance costs, reduced travel time, emissions reductions, and increases in capacity or ability to offer new types of freight or passenger services. Applicants may also describe other categories of benefits that are difficult to quantify such as noise reduction, environmental impact mitigation, improved quality of life, or reliability of travel times. All benefits claimed for the project must be clearly tied to the expected outcomes of the project. Please refer to the Benefit-Cost Analysis Guidance for Discretionary Grant Programs prior to preparing a BCA at https://www.transportation.gov/ office-policy/transportation-policy/ benefit-cost-analysis-guidance. In addition, please also refer to the BCA FAQs on FRA's website for some rail specific examples of how to apply the BCA Guidance for Discretionary Grant Programs to CRISI applications.

iii. For Tracks 1 and 4—Applicants are required to document project benefits. Any subjective estimates of benefits and costs should be quantified

whenever possible, and applicants should provide appropriate evidence to support their subjective estimates. Estimates of benefits should be presented in monetary terms whenever possible; if a monetary estimate is not possible, then a quantitative estimate (in physical, non-monetary terms, such as crash or employee casualty rates, ridership estimates, emissions levels, energy efficiency improvements, etc.) should be provided. At a minimum, qualitatively describe the project benefits.

iv. SF 424—Application for Federal Assistance;

v. SF 424A—Budget Information for Non-Construction or SF 424C—Budget Information for Construction;

vi. SF 424B—Assurances for Non-Construction or SF 424D—Assurances for Construction;

vii. FRA's Additional Assurances and Certifications; and

viii. SF LLL—Disclosure of Lobbying Activities.

Forms needed for the electronic application process are at www.Grants.gov.

c. Post-Selection Requirements

See subsection F(2) of this notice for post-selection requirements.

3. Unique Entity Identifier, System for Award Management (SAM), and Submission Instructions

To apply for funding through *Grants.gov*, applicants must be properly registered. Complete instructions on how to register and submit an application can be found at www.Grants.gov. Registering with *Grants.gov* is a one-time process; however, it can take up to several weeks for first-time registrants to receive confirmation and a user password. FRA recommends that applicants start the registration process as early as possible to prevent delays that may preclude submitting an application package by the application deadline. Applications will not be accepted after the due date. Delayed registration is not an acceptable justification for an application extension.

FRA may not make a grant award to an applicant until the applicant has complied with all applicable Data Universal Numbering System (DUNS) and SAM requirements. (Please note that if a Dun & Bradstreet DUNS number must be obtained or renewed, this may take a significant amount of time to complete.) Late applications that are the result of a failure to register or comply with *Grants.gov* applicant requirements in a timely manner will not be considered. If an applicant has not fully

complied with the requirements by the submission deadline, the application will not be considered. To submit an application through *Grants.gov*, applicants must:

a. Obtain a DUNS Number

A DUNS number is required for Grants.gov registration. The Office of Management and Budget requires that all businesses and nonprofit applicants for Federal funds include a DUNS number in their applications for a new award or renewal of an existing award. A DUNS number is a unique nine-digit sequence recognized as the universal standard for the government in identifying and keeping track of entities receiving Federal funds. The identifier is used for tracking purposes and to validate address and point of contact information for Federal assistance applicants, recipients, and subrecipients. The DUNS number will be used throughout the grant life cycle. Obtaining a DUNS number is a free, one-time activity. Applicants may obtain a DUNS number by calling 1-866-705-5711 or by applying online at http://www.dnb.com/us.

b. Register With the SAM at www.SAM.Gov

All applicants for Federal financial assistance must maintain current registrations in the SAM database. An applicant must be registered in SAM to successfully register in Grants.gov. The SAM database is the repository for standard information about Federal financial assistance applicants, recipients, and sub recipients. Organizations that have previously submitted applications via Grants.gov are already registered with SAM, as it is a requirement for Grants.gov registration. Please note, however, that applicants must update or renew their SAM registration at least once per year to maintain an active status. Therefore, it is critical to check registration status well in advance of the application deadline. If an applicant is selected for an award, the applicant must maintain an active SAM registration with current information throughout the period of the award. Information about SAM registration procedures is available at www.sam.gov.

c. Create a Grants.Gov Username and Password

Applicants must complete an Authorized Organization Representative (AOR) profile on www.Grants.gov and create a username and password. Applicants must use the organization's DUNS number to complete this step. Additional information about the

registration process is available at: https://www.grants.gov/web/grants/ applicants/organizationregistration.html.

d. Acquire Authorization for your AOR From the E-Business Point of Contact (E-Biz POC)

The E-Biz POC at the applicant's organization must respond to the registration email from *Grants.gov* and login at *www.Grants.gov* to authorize the applicant as the AOR. Please note there can be more than one AOR for an organization.

e. Submit an Application Addressing All Requirements Outlined in This NOFO

If an applicant experiences difficulties at any point during this process, please call the *Grants.gov* Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: http://www.grants.gov/web/grants/applicants/apply-for-grants.html.

Note: Please use generally accepted formats such as .pdf, .doc, .docx, .xls, .xlsx and .ppt, when uploading attachments. While applicants may embed picture files, such as .jpg, .gif, and .bmp, in document files, applicants should not submit attachments in these formats. Additionally, the following formats will not be accepted: .com, .bat, .exe, .vbs, .cfg, .dat, .db, .dbf, .dll, .ini, .log, .ora, .sys, and .zip.

4. Submission Dates and Times

Applicants must submit complete applications to www.Grants.gov no later than 5:00 p.m.. EDT, September 17, 2018. FRA reviews www.Grants.gov information on dates/times of applications submitted to determine timeliness of submissions. Late applications will be neither reviewed nor considered. Delayed registration is not an acceptable reason for late submission. In order to apply for funding under this announcement, all applicants are expected to be registered as an organization with Grants.gov. Applicants are strongly encouraged to apply early to ensure all materials are received before this deadline.

To ensure a fair competition of limited discretionary funds, the following conditions are not valid reasons to permit late submissions: (1) Failure to complete the *Grants.gov* registration process before the deadline; (2) failure to follow *Grants.gov* instructions on how to register and apply as posted on its website; (3) failure to follow all instructions in this NOFO; and (4) technical issues

experienced with the applicant's computer or information technology environment.

5. Intergovernmental Review

Executive Order 12372 requires applicants from State and local units of government or other organizations providing services within a State to submit a copy of the application to the State Single Point of Contact (SPOC), if one exists, and if this program has been selected for review by the State. Applicants must contact their State SPOC to determine if the program has been selected for State review.

6. Funding Restrictions

FRA is prohibited under 49 U.S.C. 24405(f) from providing CRISI grants for commuter rail passenger transportation (as defined in 49 U.S.C. 24102(3)) FRA's interpretation of this restriction is informed by the language in 49 U.S.C. 24407. FRA's primary intent in funding passenger rail projects is to make reasonable investments in intercity passenger rail transportation. Such projects may be located on shared corridors where Commuter Rail Passenger Transportation and/or freight rail also benefit from the project.

Consistent with 2 CFR 200.458, as applicable, FRA will only approve preaward costs if such costs are incurred pursuant to the negotiation and in anticipation of the grant agreement and if such costs are necessary for efficient and timely performance of the scope of work. Under 2 CFR 200.458, grant recipients must seek written approval from the administering agency for preaward activities to be eligible for reimbursement under the grant. Activities initiated prior to the execution of a grant or without written approval may not be eligible for reimbursement or included as a grantee's matching contribution.

7. Other Submission Requirements

If an applicant experiences difficulties at any point during this process, please call the *Grants.gov* Customer Center Hotline at 1–800–518–4726, 24 hours a day, 7 days a week (closed on Federal holidays). For information and instructions on each of these processes, please see instructions at: http://www.grants.gov/web/grants/applicants/apply-for-grants.html.

E. Application Review Information

- 1. Criteria
- a. Eligibility and Completeness Review

FRA will first screen each application for applicant and project eligibility (eligibility requirements are outlined in Section C of this notice), completeness (application documentation and submission requirements are outlined in Section D of this notice), and the 20 percent minimum match in determining whether the application is eligible.

FRA will then consider the applicant's past performance in developing and delivering similar projects and previous financial contributions, and previous competitive grant technical evaluation ratings that the proposed project received under previous competitive grant programs administered by the DOT if applicable.

b. Evaluation Criteria

FRA subject-matter experts will evaluate all eligible and complete applications using the evaluation criteria outlined in this section to determine project benefits and technical merit.

i. Project Benefits:

FRA will evaluate the Benefit-Cost Analysis of the proposed project for the anticipated private and public benefits relative to the costs of the proposed project and the summary of benefits provided in response to subsection D(2)(a)(ii) including—

(A) Effects on system and service

performance;

- (B) Effects on safety, competitiveness, reliability, trip or transit time, and resilience:
- (C) Efficiencies from improved integration with other modes; and
- (D) Ability to meet existing or anticipated demand.

ii. Technical Merit:

FRA will evaluate application information for the degree to which—

(A) The tasks and subtasks outlined in the SOW are appropriate to achieve the expected outcomes of the proposed project.

(B) Applications indicate strong project readiness and meet requirements under the project track(s) designated by

the applicant.

- (C) The technical qualifications and experience of key personnel proposed to lead and perform the technical efforts, and the qualifications of the primary and supporting organizations to fully and successfully execute the proposed project within the proposed timeframe and budget are demonstrated.
- (D) The proposed project's business plan considers potential private sector participation in the financing, construction, or operation of the proposed project.
- (E) The applicant has, or will have the legal, financial, and technical capacity to carry out the proposed project; satisfactory continuing control over the use of the equipment or facilities; and

the capability and willingness to maintain the equipment or facilities.⁷

(F) The proposed project is consistent with planning guidance and documents set forth by DOT, including those required by law or State rail plans developed under Title 49, United State Code, Chapter 227.

c. Selection Criteria

In addition to the eligibility and completeness review and the evaluation criteria outlined in this subsection, the FRA Administrator will select projects applying the following selection criteria:

i. The Administrator will give preference to projects for which the:

(A) Proposed Federal share of total project costs is 50 percent or less;

- (B) Proposed non-Federal share is comprised of more than one source, including private sources, demonstrating broad participation by affected stakeholders;
 - and
- (C) Net benefits of the grant funds will be maximized considering the Benefit-Cost Analysis, including anticipated private and public benefits relative to the costs of the proposed project, and factoring in the other considerations in 49 U.S.C. 24407(e).
- ii. After applying the above preferences, the FRA Administrator will take into account the following key Departmental objectives:
- (A) Supporting economic vitality at the national and regional level;
- (B) Leveraging Federal funding to attract other, non-Federal sources of infrastructure investment;
- (C) Preparing for future operations and maintenance costs associated with their project's life-cycle, as demonstrated by a credible plan to maintain assets without having to rely on future federal funding.
- (D) Using innovative approaches to improve safety and expedite project delivery; and,
- (E) Holding grant recipients accountable for their performance and achieving specific, measurable outcomes identified by grant applicants.
- 2. Review and Selection Process

FRA will conduct a three-part application review process, as follows:

 a. Screen applications for completeness and eligibility;

- b. Evaluate eligible applications (completed by technical panels applying the evaluation criteria); and
- c. Select projects for funding (completed by the FRA Administrator applying the selection criteria).
- 3. Reporting Matters Related to Integrity and Performance

Before making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold of \$150,000 (see 2 CFR 200.88 Simplified Acquisition Threshold), FRA will review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). See 41 U.S.C. 2313.

An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.

FRA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2 CFR 200.205.

F. Federal Award Administration Information

1. Federal Award Notice

FRA will announce applications selected for funding in a press release and on the FRA website after the application review period. FRA will contact applicants with successful applications after announcement with information and instructions about the award process. This notification is not an authorization to begin proposed project activities. A formal cooperative agreement or grant agreement signed by both the grantee and the FRA, including an approved scope, schedule, and budget, is required to obligate the grant.

For all projects, obligation occurs when a selected applicant and FRA enter a written project specific cooperative agreement or grant agreement and is after the applicant has satisfied applicable requirements. For Track 2 PE/NEPA projects, these requirements may include transportation planning. For Track 3 FD/Construction projects, these

⁷ FRA will not preclude projects for the initiation or restoration of Intercity Passenger Rail Service under 49 U.S.C. 24407(c)(2) from consideration for funding due to a lack of agreement among the funding recipients, operator, and host railroad regarding access to and use of the host railroad facilities, if an agreement or order for the use of such facilities may occur under 49 U.S.C. 24308.

requirements may include transportation planning, PE and environmental reviews.

2. Administrative and National Policy Requirements

Due to funding limitations, projects that are selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate the proposed projects are still viable and can be completed with the amount awarded.

Grantees and entities receiving funding from the grantee, must comply with all applicable laws and regulations. Examples of administrative and national policy requirements include: 2 CFR part 200; procurement standards; compliance with Federal civil rights laws and regulations; requirements for disadvantaged business enterprises, debarment and suspension requirements, and drug-free workplace requirements; FRA's and OMB's Assurances and Certifications; Americans with Disabilities Act; safety requirements; NEPA; environmental justice requirements; performance

measures under 49 U.S.C. 24407(f); 49 U.S.C. 24405, including the Buy America requirements and the provision deeming operators rail carriers for certain purposes.

See an example of standard terms and conditions for FRA grant awards at https://www.fra.dot.gov/Elib/Document/14426.

3. Reporting

a. Progress Reporting on Grant Activity

Each applicant selected for a grant will be required to comply with all standard FRA reporting requirements, including quarterly progress reports, quarterly Federal financial reports, and interim and final performance reports, as well as all applicable auditing, monitoring and close out requirements. Reports may be submitted electronically.

b. Additional Reporting

Applicants selected for funding are required to comply with all reporting requirements in the standard terms and conditions for FRA grant awards including 2 CFR 180.335 and 2 CFR 180.350. See an example of standard

terms and conditions for FRA grant awards at: https://www.fra.dot.gov/eLib/ Details/L19057.

If the Federal share of any Federal award under this NOFO may include more than \$500,000 over the period of performance, applicants are informed of the post award reporting requirements reflected in 2 CFR part 200, Appendix XII—Award Term and Condition for Recipient Integrity and Performance Matters.

c. Performance Reporting

Each applicant selected for funding must collect information and report on the project's performance using measures mutually agreed upon by FRA and the grantee to assess progress in achieving strategic goals and objectives. Examples of some rail performance measures are listed in the table below. The applicable measure(s) will depend upon the type of project. Applicants requesting funding for the acquisition of rolling stock must integrate at least one equipment/rolling stock performance measure, consistent with the grantee's application materials and program goals.

| , 1 | 1 | | | · · | |
|---------------------------------|---------------|----------|---------------------------|-------------------------------|--|
| Rail measures | Unit measured | Temporal | Primary strategic goal | Secondary stra- tegic goal | Description |
| Slow Order Miles | Miles | Annual | State of Good Repair. | Safety | The number of miles per year within the project area that have temporary speed restrictions ("slow orders") imposed due to track condition. This is an indicator of the overall condition of track. This measure can be used for projects to rehabilitate sections of a rail line since the rehabilitation should eliminate, or at least reduce the slow orders upon project completion. |
| Gross Ton | Gross Tons | Annual | Economic Competitiveness. | State of Good Repair. | The annual gross tonnage of freight shipped in the project area. Gross tons include freight cargo minus tare weight of the rail cars. This measure the volume of freight a railroad ships in a year. This measure can be useful for projects that are anticipated to increase freight shipments. |
| Rail Track Grade Separation. | Count | Annual | Economic Competitiveness. | Safety | The number of annual automobile crossings that are eliminated at an at-grade crossing as a result of a new grade separation. |
| Passenger Counts | Count | Annual | Economic Competitiveness. | State of Good Repair. | Count of the annual passenger boardings and alightings at stations within the project area. |
| Travel Time | Time/Trip | Annual | Economic Competitiveness. | Quality of Life | Point-to-point travel times between pre-determined station stops within the project area. This measure demonstrates how track improvements and other upgrades improve operations on a rail line. It also helps make sure the railroad is maintaining the line after project completion. |

| Rail measures | Unit measured | Temporal | Primary strategic goal | Secondary stra- tegic goal | Description |
|------------------------|---------------|----------|------------------------|-------------------------------|---|
| Track weight capacity. | Yes/No | One Time | State of Good Repair. | Economic Competitiveness. | If a project is upgrading a line to accommodate heavier rail cars (typically an increase from 263,000 lb. rail cars to 286,000 lb. rail cars.) |
| Track Miles | Miles | One Time | State of Good Repair. | Economic Competitiveness. | The number of track miles that exist within the project area. This measure can be beneficial for projects building sidings or sections of additional main line track on a railroad. |

G. Federal Awarding Agency Contacts

For further information regarding this notice and the grants program, please contact Ms. Amy Houser, Office of Program Delivery, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W36–412, Washington, DC 20590; email: amy.houser@dot.gov; phone: 202–493–0303, or Ms. Frances Bourne, Office of Policy and Planning, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–207, Washington, DC 20590; email: frances.bourne@dot.gov; phone: 202–493–6366.

H. Other Information

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. If the application includes information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant should do the following: (1) Note on the front cover that the submission "Contains Confidential Business Information (CBI)"; (2) mark each affected page "CBI"; and (3) highlight or otherwise denote the CBI portions.

DOT protects such information from disclosure to the extent allowed under applicable law. In the event DOT receives a Freedom of Information Act (FOIA) request for the information, DOT will follow the procedures described in its FOIA regulations at 49 CFR 7.17. Only information that is ultimately determined to be confidential under that procedure will be exempt from disclosure under FOIA.

Issued in Washington, DC, on July 11, 2018.

Ronald Louis Batory,

Administrator, Federal Railroad Administration.

[FR Doc. 2018–15412 Filed 7–18–18; 8:45 am]

BILLING CODE 4910-06-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0111]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel ACQUA BLU; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 20, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0111. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel ACQUA BLU is:

- —Intended Commercial Use of Vessel: "Day charter operations in Miami, Florida"
- -Geographic Region: ''Florida'' The complete application is given in DOT docket MARAD-2018-0111 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * * * Dated: July 16, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.
[FR Doc. 2018–15432 Filed 7–18–18; 8:45 am]
BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0112]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel VENOM; Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

August 20, 2018.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief

description of the proposed service, is listed below. **DATES:** Submit comments on or before

ADDRESSES: Comments should refer to docket number MARAD 2018 0112. Written comments may be submitted by hand or by mail to the Docket Clerk. U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DČ 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at

FOR FURTHER INFORMATION CONTACT:

http://www.regulations.gov.

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel VENOM is:

- —Intended Commercial Use of Vessel: "Carry passengers on day charters for sightseeing, snorkeling, etc."
- —Geographic Region: "Hawaii, California"

The complete application is given in DOT docket MARAD 2018 0112 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121. * * *

Dated: July 16, 2018.

By Order of the Maritime Administrator. **T. Mitchell Hudson, Jr.,**

Secretary, Maritime Administration. [FR Doc. 2018-15430 Filed 7-18-18; 8:45 am]

BILLING CODE 4910-81-P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD-2018-0113]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel MONTRACHET; Invitation for Public Comments

AGENCY: Maritime Administration, DOT. **ACTION:** Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before August 20, 2018.

ADDRESSES: Comments should refer to docket number MARAD-2018-0113. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590. You may also send comments electronically via the internet at http://www.regulations.gov. All comments will become part of this docket and will be available for inspection and copying at the above address between 10:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202– 366–9309, Email *Bianca.carr@dot.gov*.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel MONTRACHET is:

- —Intended Commercial Use of Vessel: "Time Charters"
- —Geographic Region: "Florida, Delaware, New Jersey, New York (excluding New York Harbor), Connecticut, Rhode Island, Massachusetts, New Hampshire, Maine"

The complete application is given in DOT docket MARAD-2018-0113 at http://www.regulations.gov. Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the

comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT/MARAD solicits comments from the public to better inform its rulemaking process. DOT/MARAD posts these comments, without edit, to www.regulations.gov, as described in the system of records notice, DOT/ALL-14 FDMS, accessible through www.dot.gov/privacy. In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

Dated: July 16, 2018.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration. [FR Doc. 2018–15431 Filed 7–18–18; 8:45 am] BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA-2018-0028]

Pipeline Safety: Pipeline Research and Development Forum

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of public forum.

SUMMARY: This notice is to inform the interested public that the Pipeline and Hazardous Materials Safety
Administration (PHMSA), Office of Pipeline Safety (OPS) will be conducting a public meeting for the Pipeline Research and Development Forum. PHMSA periodically conducts such a forum to generate a national research agenda that fosters solutions to the many challenges with pipeline safety and protecting the environment.

DATES: The public forum will be held on September 11–12, 2018. Name badge

pick up and on-site registration will be available starting at 7:00 a.m. on both days, with the forum taking place from 8:00 a.m. ET until approximately 5:00 p.m. ET on September 11 and from 8:00 a.m. ET until approximately 4:30 p.m. ET on September 12. Online preregistration for the forum is available until August 27. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, should notify OPS by August 27. For additional information, see the ADDRESSES section of this notice.

ADDRESSES: The public forum will be held at the Hyatt Regency Baltimore Inner Harbor Hotel, 300 Light Street, Baltimore, Maryland, 21202. The agenda and any additional information for the forum will be published on the following meeting and registration page at https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=136.

Registration: To help assure that adequate space is provided, attendees should register in advance at the PHMSA public forum website at https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=136. Onsite registration will also be available.

The public forum will not be webcast; however, presentations will be available on the forum website and in the public docket at https://www.regulations.gov/, in docket number PHMSA-2018-0028, within 30 days following the meeting.

Public Participation: The Pipeline Research and Development Forum will be open to the public. Members of the public will be provided an opportunity to make a statement during the forum.

Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, should notify Robert Smith, Engineering and Research Division, at 919–238–4759 or robert.w.smith@dot.gov.

Written comments: Persons who wish to submit written comments on the forum may do so by submitting them to the public docket in the following ways:

E-Gov website: https:// www.regulations.gov. This website allows the public to enter comments on any Federal Register notice issued by any agency.

Fax: 1-202-493-2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays.

Instructions: Identify the docket number PHMSA-2018-0028 at the beginning of your comments. Note that all comments received will be posted without change to https:// www.regulations.gov, including any personal information provided. Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, consider reviewing DOT's complete Privacy Act Statement in the Federal Register published on April 11, 2000 (65 FR 19477), or view the Privacy Notice at https://www.regulations.gov before submitting comments.

Docket: For docket access or to read background documents or comments, go to https://www.regulations.gov at any time or to Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: "Comments on PHMSA—2018—0028." The docket clerk will date stamp the postcard prior to returning it to you via the U.S. mail.

Privacy Act Statement

DOT may solicit comments from the public regarding certain general notices. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT:

Robert Smith, Office of Pipeline Safety, Engineering and Research Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, at 919–238–4759 or robert.w.smith@dot.gov.

SUPPLEMENTARY INFORMATION: PHMSA periodically conducts this Pipeline Research and Development Forum to generate a national research agenda that fosters solutions to the many challenges with pipeline safety and protecting the environment. The forum allows the public, government and industry pipeline stakeholders to provide input on the technical gaps and challenges for future research. It also reduces duplication of programs, factors ongoing research efforts, leverages resources and broadens synergies. The national

research agenda that will be developed through this forum will help PHMSA align its research program with the needs of its pipeline safety mission and make use of the best available knowledge and expertise, as well as considering the perspectives of stakeholders.

Issued in Washington, DC on July 11, 2018, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety. [FR Doc. 2018-15418 Filed 7-18-18; 8:45 am] BILLING CODE 4910-60-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Proposed Information Collection; Comment Request; Renewal Without Change of Bank Secrecy Act **Regulations Requiring Money Services Businesses To Report Suspicious** Activity

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), U.S. Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: FinCEN, a bureau of the U.S. Department of the Treasury ("Treasury"), invites all interested parties to comment on its proposed renewal without change of the Bank Secrecy Act ("BSA") Suspicious Activity Reporting requirements for money services businesses ("MSBs"). FinCEN intends to submit this requirement for approval by the Office of Management and Budget ("OMB") of a three-year renewal of Control Number 1506–0015. This request for comments is made pursuant to the Paperwork Reduction Act ("PRA") of 1995, Public Law 104-13, 44 U.S.C. 3506(c)(2)(A). **DATES:** Written comments should be received on or before September 17, 2018 to be assured of consideration. ADDRESSES: Comments may be submitted by any of the following

- methods: Federal E-rulemaking Portal: http:// www.regulations.gov. Follow the instructions for submitting comments. Refer to Docket Number FINCEN-2018-0006 and the specific OMB control number 1506-0015.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN-2018-0006 and the specific OMB control number 1506-0015.

Please submit comments by one method only. Comments will also be

incorporated to FinCEN's retrospective regulatory review process, as mandated by E.O. 12866 and 13563. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at 800-767-2825 or electronically at frc@fincen.gov. SUPPLEMENTARY INFORMATION: The BSA, Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C. 1951–1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, among other things, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement countermoney laundering programs and compliance procedures.¹ Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury to administer the BSA has been delegated to the Director of FinCEN. The information collected and retained under the regulation addressed in this notice assist Federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation, and prosecution of money laundering and other matters. In accordance with the requirements of the PRA, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is presented concerning the recordkeeping requirements listed below.

1. Title: Suspicious Activity Report by Money Services Businesses.

OMB Number: 1506-0015.

Abstract: In accordance with 31 CFR 1022.320, covered financial institutions are required to report suspicious activity and maintain the records for a period of five years. Covered financial institutions may satisfy these requirements by using their internal records management system.

Current Action: Renewal without change to the existing regulations.

Type of Review: Renewal of currently

approved reporting requirement.

Affected Public: Businesses and other for-profit institutions.

Estimated Burden: The administrative burden of 1 hour is assigned to maintain the requirement in force. The burden for actual reporting is reflected in OMB Control number 1506-0065.

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. Records required to be retained under the BSA must be retained for five years. Generally, information collected pursuant to the BSA is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

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.

Jamal El-Hindi,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2018-15400 Filed 7-18-18; 8:45 am] BILLING CODE 4810-02-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; **Comment Request; Renewal Without Change of Anti-Money Laundering Programs for Insurance Companies** and Non-Bank Residential Mortgage **Lenders and Originators**

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), U.S. Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: FinCEN invites comment on the renewal of information collections in existing regulations requiring

 $^{^{\}mbox{\tiny 1}}\mbox{Language}$ expanding the scope of the Bank Secrecy Act to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56.

insurance companies and non-bank residential mortgage lenders and originators to develop and implement written anti-money laundering programs reasonably designed to prevent those financial institutions from being used to facilitate money laundering and the financing of terrorist activities. This request for comments is being made pursuant to the Paperwork Reduction Act ("PRA") of 1995.

DATES: Written comments are welcome and must be received on or before September 17, 2018.

ADDRESSES: Comments may be submitted by any of the following methods:

- Federal E-rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Refer to Docket Number FINCEN-2018-0004 and OMB control number 1506-0035.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2018–0004 and OMB control number 1506–0035.

Please submit comments by one method only. Comments will also be incorporated to FinCEN's retrospective regulatory review process, as mandated by E.O. 12866 and 13563. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at 800–767–2825 or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION: The Bank Secrecy Act ("BSA"), Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C.1951-1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, among other things, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.1

Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury to administer the BSA has been delegated to the Director of FinCEN.

The information collected and retained under the regulations addressed in this notice assists Federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation, and prosecution of money laundering and other matters. In accordance with the requirements of the PRA, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is presented concerning the recordkeeping requirements listed below.

Title: Anti-money laundering programs for insurance companies, 31 CFR 1025.210 and non-bank residential mortgage lenders and originators, 31 CFR 1029 210

Office of Management and Budget ("OMB") Control Number: 1506–0035.

Abstract: Insurance companies and non-bank residential mortgage lenders and originators are required to establish and maintain written anti-money laundering programs. A copy of the written program must be maintained for five years.

Current Action: Renewal without change of current regulations.

Type of Review: Renewal of a currently approved information collection.

Affected Public: Businesses and other for-profit institutions.

Estimated Number of Respondents: 1,200 Insurance Companies and 31,000 Non-Bank Residential Mortgage Lender and Originators.

Estimated Number of Responses: 1,200 Insurance Companies and 31,000 Non-Bank Residential Mortgage Lender and Originators.

Estimated Number of Hours: 1,200 Insurance Companies and 31,000 Non-Bank Residential Mortgage Lender and Originators.²

Total Estimated Burden Hours: 32,200.

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. Records required to be retained under the BSA must be retained for five years. Generally, information collected pursuant to the BSA is confidential but may be shared as provided by law with regulatory and law enforcement authorities.

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.

Jamal El-Hindi,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2018-15401 Filed 7-18-18; 8:45 am]

BILLING CODE 4810-02-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Proposed Collection; Comment Request; Renewal Without Change of the Registration of Money Services Business, Regulation and FinCEN Form 107

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, FinCEN invites comment on a renewal without change to a currently approved information collection contained in 31 CFR 1022.380 and the Registration of Money Services Business report, FinCEN Form 107. The form will be used by currency dealers or exchangers; check cashers; issuers of traveler's checks, money orders or prepaid access; sellers of traveler's checks, money orders or prepaid access; redeemers of traveler's checks, money orders or prepaid access; and money transmitters to register with the Department of the Treasury as required by statute. This request for comments is being made pursuant to the Paperwork Reduction Act of 1995, Public Law 104-13, 44 U.S.C. 3506(c)(2)(A).

DATES: Written comments are welcome and must be received on or before September 17, 2018 to be assured of consideration.

¹Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56.

² This is a renewal without change of a current program. The annual update to a financial institutions' AML program is one (1) hour.

ADDRESSES: Comments may be submitted by any of the following methods:

- Federal E-rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Refer to Docket Number FINCEN-2018-0005 and the specific OMB control number 1506-0013.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2018–0005 and the specific OMB control number 1506–0013.

Please submit comments by one method only. Comments will also be incorporated to FinCEN's retrospective regulatory review process, as mandated by E.O. 12866 and 13563. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at 800–767–2825 or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION: The Bank Secrecy Act ("BSA"), Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, among other things, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counterintelligence activities to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.1

Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury to administer the BSA has been delegated to the Director of FinCEN.

The information collected and retained under the regulations addressed in this notice assists Federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation, and prosecution of money laundering and other matters. In accordance with the requirements of the PRA, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is

presented concerning the recordkeeping requirements listed below.

Title: Registration of Money Services Business.

OMB Number: 1506-0013. Form Number: FinCEN Form 107. Abstract: The statute generally referred to as the "Bank Secrecy Act," Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829b. 12 U.S.C. 1951–1959, and 31 U.S.C. 5311-5330, authorizes the Secretary of the Treasury, among other things, to issue regulations requiring records and reports that are determined to have a high degree of usefulness in criminal. tax, and regulatory matters. Regulations implementing Title II of the Bank Secrecy Act (codified at 31 U.S.C. 5311-5330) appear at 31 CFR Chapter X. The authority of the Secretary to administer the Bank Secrecy Act has been

delegated to the Director of FinCEN. Under 31 U.S.C. 5330 and its implementing regulations, money services businesses must register with the Department of the Treasury, maintain a list of their agents, and renew their registration every two years. Currently, money services businesses register by filing FinCEN Form 107, which is being renewed without change. The information collected on the form is required to comply with 31 U.S.C. 5330 and its implementing regulations. The information will be used to assist supervisory and law enforcement agencies in the enforcement of criminal, tax, and regulatory laws and to prevent money services businesses from being used by those engaging in money laundering. The collection of information is mandatory.

Current Actions: The current Form 107 and instructions are being renewed without change.

Type of Review: Renewal of currently approved collection report.

Affected public: Business or other forprofit institutions.

Frequency: As required.

Estimated Burden: Reporting average of 30 minutes per response; recordkeeping average of 30 minutes per response.

Estimated number of respondents:

Estimated Total Annual Burden Hours: 42,000 hours.

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. Records required to be retained under the Bank Secrecy Act must be retained for five years. Generally, information collected pursuant to the Bank Secrecy Act is confidential, but may be shared

as provided by law with regulatory and law enforcement authorities.

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.

Jamal El-Hindi,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2018–15399 Filed 7–18–18; 8:45 am]

BILLING CODE 4810-02-P

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Proposed Information Collection; Comment Request; Renewal Without Change of Bank Secrecy Act Suspicious Activity Reporting Non-Bank Requirement for Residential Mortgage Lenders and Originators

AGENCY: Financial Crimes Enforcement Network ("FinCEN"), U.S. Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: FinCEN, a bureau of the U.S. Department of the Treasury ("Treasury"), invites all interested parties to comment on its proposed renewal without change of the Bank Secrecy Act ("BSA") Suspicious Activity Reporting regulatory requirements for residential mortgage lenders and originators. FinCEN intends to submit this requirement for approval by the Office of Management and Budget ("OMB") of a three-year renewal of Control Number 1506-0061. This request for comments is made pursuant to the Paperwork Reduction Act ("PRA") of 1995.

DATES: Written comments should be received on or before September 17, 2018 to be assured of consideration.

¹Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56.

ADDRESSES: Comments may be submitted by any of the following methods:

- Federal E-rulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Refer to Docket Number FINCEN-2018-0007 and the OMB control number 1506-0061.
- Mail: Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2018–0007 and the OMB control number 1506–0061. Please submit comments by one method only (electronically preferred). All comments submitted in response to this notice will become a matter of public record. Comments will also be incorporated to FinCEN's retrospective regulatory review process, as mandated by E.O. 12866 and 13563. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Resource Center at 800–767–2825 or electronically at frc@fincen.gov.

SUPPLEMENTARY INFORMATION: The BSA, Titles I and II of Public Law 91-508, as amended, codified at 12 U.S.C. 1829(b), 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5332, authorizes the Secretary of the Treasury, among other things, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism, and to implement countermoney laundering programs and compliance procedures.1

Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary of the Treasury to administer the BSA has been delegated to the Director of FinCEN. The information collected and retained under the regulation addressed in this notice assist Federal, state, and local law enforcement as well as regulatory authorities in the identification, investigation, and prosecution of money laundering and other matters. In accordance with the requirements of the PRA, 44 U.S.C. 3506(c)(2)(A), and its implementing regulations, the following information is presented concerning the recordkeeping requirements listed below.

Title: Suspicious Activity Report by Non-Bank Residential Mortgage Lenders and Originators.

OMB Number: 1506-0061.

Abstract: In accordance with 31 CFR 1029.320, covered financial institutions are required to report suspicious activity and maintain the records for a period of five years. Covered financial institutions may satisfy these requirements by using their internal records management system.

Current Action: Renewal without change to the existing regulations.

Type of Review: Renewal of currently approved reporting requirement.

Affected Public: Businesses or other for-profit institutions.

Burden: The administrative burden of 1 hour is assigned to maintain the requirement in force. The burden for actual reporting is reflected in OMB Control number 1506–0065.

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. Records required to be retained under the BSA must be retained for five years. Generally, information collected pursuant to the BSA is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

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.

Jamal El Hindi,

Deputy Director, Financial Crimes Enforcement Network.

[FR Doc. 2018-15402 Filed 7-18-18; 8:45 am]

BILLING CODE 4810-02-P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (www.treas.gov/ofac).

Notice of OFAC Actions

On July 9, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked under the relevant sanctions authorities listed below.

Entity

1. MAHAN TRAVEL AND TOURISM SDN BHD (a.k.a. MAHAN TRAVEL), No.01, Lower Ground Floor, Block C, NO:12 Megan Avenue2, Jalan Yap, Kwan Seng, Kuala Lumpur, Malaysia; website http://mahantravel.com.my; Email Address mahankualalumpur@yahoo.com; Additional Sanctions Information—Subject to Secondary Sanctions; Registration Number 875233—U (Malaysia) [SDGT] [IFSR] (Linked To: MAHAN AIR).

Designated pursuant to section 1(c) of E.O. 13224 for acting for or on behalf of Iran's MAHAN AIR, a person

¹Language expanding the scope of the Bank Secrecy Act to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107–56.

determined to be subject to E.O. 13224, and section 1(d)(i) of E.O. 13224 for assisting in, sponsoring, or providing financial, material, technological support for, or financial or other services to or in support of, MAHAN AIR.

Dated: July 9, 2018.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets

[FR Doc. 2018–15470 Filed 7–18–18; 8:45 am]

BILLING CODE 4810-AL-P

DEPARTMENT OF VETERANS AFFAIRS

Solicitation of Nomination for Appointment to the Advisory Committee on Women Veterans

ACTION: Notice.

SUMMARY: The Department of Veterans Affairs (VA) is seeking nominations of qualified candidates to be considered for membership on the Advisory Committee on Women Veterans ("the Committee") for the 2018 membership cycle.

DATES: Nominations for membership on the Committee must be received by August 15, 2018, no later than 4:00 p.m., eastern standard time. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nomination packages should be sent to the Advisory Committee Management Office by email (recommended) or mail. Please see contact information below.

Advisory Committee Management Office (00AC), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC, 20420, VA.Advisory.Cmte@va.gov.

SUPPLEMENTARY INFORMATION: In

carrying out the duties set forth, the Committee responsibilities include, but are not limited to provides a Congressionally-mandated report to the Secretary each even-numbered year, which includes:

- (1) An assessment of the needs of women Veterans with respect to compensation, health care, rehabilitation, outreach, and other benefits and programs administered by VA;
- (2) A review of the programs and activities of VA designed to meet such needs; and
- (3) Proposing recommendation (including recommendations for administrative and legislative action) as the Committee considers appropriate.

The Committee reports to the Secretary, through the Director of the Center for Women Veterans.

Authority: The Committee is authorized by 38 U.S.C. § 542, to provide advice to the Secretary of Veterans Affairs (Secretary) on: The administration of VA's benefits and services (health care, rehabilitation benefits, compensation, outreach, and other relevant programs) for women Veterans; reports and studies pertaining to women Veterans; and the needs of women Veterans. In accordance with the Statute and the Committee's current charter, the majority of the membership shall consist of non-Federal employees appointed by the Secretary from the general public, serving as special government employees.

The Secretary appoints Committee members, and determines the length of terms in which Committee members serve. A term of service for any member may not exceed 3 years. However, the Secretary can reappoint members for additional terms. Each year, there are several vacancies on the Committee, as members' terms expire.

Membership Criteria: The Committee is currently comprised of 12 members. By statute, the Committee consists of members appointed by the Secretary from the general public, including: representatives of women Veterans; individuals who are recognized authorities in fields pertinent to the needs of women Veterans, including the gender specific health-care needs of women; representatives of both female and male Veterans with serviceconnected disabilities, including at least one female Veteran with a serviceconnected disability and at least one male Veteran with a service-connected disability; and women Veterans who are recently separated from service in the Armed Forces.

The Committee meets at least two times annually, which may include a site visit to a VA field location. In accordance with Federal Travel Regulation, VA will cover travel expenses—to include per diem—for all members of the Committee, for any travel associated with official Committee duties. A copy of the Committee's most recent charter and a list of the current membership can be found at www.va.gov/ADVISORY/ or www.va.gov/womenvet/. Selfnominations are acceptable. Any letters of nomination from organizations or other individuals should accompany the package when it is submitted. Non-Veterans are also eligible for nomination.

In accordance with recently revised guidance regarding the ban on lobbyists serving as members of advisory boards and commissions, Federally-registered lobbyists are prohibited from serving on Federal advisory committees in an individual capacity. Additional information regarding this issue can be found at www.federalregister.gov/articles/2014/08/13/2014–19140/revised-guidance-on-appointment-of-lobbyists-to-federal-advisory-committees-boards-and-commissions.

Requirements for Nomination Submission

Nomination packages must be typed (12 point font) and include: (1) A cover letter from the nominee, and (2) a current resume that is no more than four pages in length. The cover letter must summarize: the nominees' interest in serving on the committee and contributions she/he can make to the work of the committee; any relevant Veterans service activities she/he is currently engaged in; the military branch affiliation and timeframe of military service (if applicable). To promote inclusion and demographic balance of membership, please include as much information related to your race, national origin, disability status, or any other factors that may give you a diverse perspective on women Veterans matters. Finally, please include in the cover letter the nominee's complete contact information (name, address, email address, and phone number); and a statement confirming that she/he is not a Federally-registered lobbyist. The resume should show professional work experience, and Veterans service involvement, especially service that involves women Veterans' issues.

The Department makes every effort to ensure that the membership of its advisory committees is fairly balanced, in terms of points of view represented. In the review process, consideration is given to nominees' potential to address the Committee's demographic needs (regional representation, race/ethnicity representation, professional expertise, war era service, gender, former enlisted or officer status, branch of service, etc.). Other considerations to promote a balanced membership include longevity of military service, significant deployment experience, ability to handle complex issues, experience running large organizations, and ability to contribute to the gender-specific health care and benefits needs of women Veterans.

Dated: July 13, 2018.

Jelessa M. Burney,

Federal Advisory Committee Management Office.



FEDERAL REGISTER

Vol. 83 Thursday,

No. 139 July 19, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS-1691-P]

RIN 0938-AT28

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would update and make revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019. This rule also proposes to update the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, it proposes a rebasing of the ESRD market basket for CY 2019. This proposed rule also proposes to update requirements for the ESRD Quality Incentive Program (QIP), and to make technical amendments to correct existing regulations related to the CBP for certain DMEPOS. Finally, this proposed rule proposes changes to bidding and pricing methodologies under the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive bidding program (CBP); adjustments to DMEPOS Fee Schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multifunction ventilators or ventilators that perform functions of other durable medical equipment (DME); and payment methodology revisions for mail order items furnished in the Northern Mariana Islands. This rule also includes a request for information related to establishing fee schedule amounts for

new DMEPOS items and services. It also includes Requests for Information on promoting interoperability and electronic healthcare information exchange, and improving beneficiary access to dialysis facility and DMEPOS charge information.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 10, 2018.

ADDRESSES: In commenting, please refer to file code CMS-1691-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

- 1. *Electronically*. You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the "Submit a comment" instructions.
- 2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1691-P, P.O. Box, 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1691-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

DMEPOS@cms.hhs.gov, for issues related to DMEPOS payment policy.

Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP technical amendments only.

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

website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments.

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System (FDsys)*, a service of the United States Government Printing Office. This database can be accessed via the internet at http://www.gpo.gov/fdsys/.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

- I. Executive Summary
 - A. Purpose
 - 1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
 - Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)
 - 3. End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)
 - 4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules
 - B. Summary of the Major Provisions
 - 1. ESRD PPS
 - 2. Payment for Renal Dialysis Services Furnished to Individuals With AKI
 - 3. ESRD QIP
 - 4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules
 - C. Summary of Cost and Benefits
 - 1. Impacts of the Proposed ESRD PPS
- 2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI
- 3. Impacts of the Proposed ESRD QIP
- 4. Impacts of the Proposed Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules
- II. Calendar Year (CY) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
 - A. Background
 - B. Provisions of the Proposed Rule
 - C. Solicitation for Information on Transplant and Modality Requirements
- III. CY 2019 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)
 - A. Background
 - B. Annual Payment Rate Update for CY 2019
- IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
 - A. Background
- B. Proposed Update to Requirements Beginning With the PY 2021 ESRD QIP
- C. Proposed Requirements for the PY 2022 ESRD QIP
- D. Proposed Requirements Beginning With the PY 2024 ESRD QIP

- V. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)
 - A. Background
 - B. Current Method for Submitting Bids and Selecting Winners
 - C. Current Method for Establishing SPAs
 - D. Provisions of the Proposed Rule
- VI. Adjustments to DMEPÔS Fee Schedule Amounts Based on Information From the DMEPOS CBP
 - A. Background
- B. Current Issues
- C. Provisions of the Proposed Rule
- VII. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes
 - A. Background
- B. Provisions of the Proposed Rule
- VIII. Payment for Multi-Function Ventilators
 - A. Background
 - B. Current Issues
 - C. Provisions of the Proposed Rule
- IX. Including the Northern Mariana Islands in Future National Mail Order CBPs
 - A. Background
 - B. Current Issues
 - C. Provisions of the Proposed Rule
- X. Request for Information on the Gap-Filling Process for Establishing Fees for New DMEPOS Items
- XI. DMEPOS CBP Technical Amendments
 - A. Background
- B. Proposed Technical Amendments
- XII. Burden Reduction on Comorbidities
- A. Background
- B. Proposed Documentation Requirements
- XIII. Requests for Information
 - A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers
 - B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information
- XIV. Collection of Information Requirements
- XV. Response to Comments
- XVI. Economic Analyses
 - A. Regulatory Impact Analysis
 - B. Detailed Economic Analysis
 - C. Accounting Statement
- XVII. Regulatory Flexibility Act Analysis XVIII. Unfunded Mandates Reform Act Analysis
- XIX. Federalism Analysis
- XX. Reducing Regulation and Controlling Regulatory Costs
- XXI. Congressional Review Act
- XXII. Files Available to the Public via the Internet

Regulations Text

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD)

- Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111-148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule proposes updates and revisions to the ESRD PPS for CY
- Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule proposes to update the AKI payment rate for CY 2019.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized under section 1881(h) of the Social Security Act (the Act), and is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This proposed rule proposes a number of updates for the ESRD QIP.

- 4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules
- i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): This rule proposes to revise the DMEPOS CBP by implementing lead item pricing based on maximum winning bid amounts.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on *Information from the DMEPOS CBP:* This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: We are proposing to establish new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. We are also proposing to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: This rule proposes to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs: This rule proposes to amend § 414.210(g)(7) to indicate that beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph would no longer apply.

B. Summary of the Major Provisions

1. ESRD PPS

- Update to the ESRD PPS base rate for CY 2019: The proposed CY 2019 ESRD PPS base rate is \$235.82. This proposed amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.5 percent), and application of the wage index budget-neutrality adjustment factor (0.999833), equaling \$235.82 (\$232.37 \times 1.0150 \times 0.999833 = \$235.82).
- Annual update to the wage index: We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2019, we propose to increase the wage index floor, for areas with wage index values below the floor, to 0.5000 and are proposing to update the wage index values to the latest available data.
- *Update to the outlier policy:* We are proposing to update the outlier policy using the most current data, as well as update the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2019 using CY 2017 claims data. Based on the use of the latest available data, the proposed FDL amount for pediatric beneficiaries would increase from \$47.79 to \$47.88 and the MAP amount would decrease from \$37.31 to \$35.62, as compared to CY 2018 values. For adult beneficiaries, the proposed FDL amount would decrease from \$77.54 to \$69.73 and the MAP amount would decrease from \$42.41 to \$40.25. The 1 percent target for outlier payments was not achieved in CY 2017. Outlier payments represented approximately 0.8 percent of total payments rather than 1.0 percent. We believe using CY 2017 claims data to update the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage. We are also soliciting comment on whether we should expand the outlier policy to

include composite rate drugs and supplies.

- Update to the Drug Designation Process: We are proposing to update and revise our designation process and expand the transitional drug add-on payment adjustment (TDAPA) to all new drugs, not just those in new functional categories, and change the basis of determining the TDAPA from pricing methodologies under section 1847A of the Act, (which includes ASP +6) to ASP +0.
- *Update to the Low-Volume Payment Adjustment:* We are proposing revisions to the low-volume payment adjustment regulations to allow for more flexibility with regard to attestation dates and cost reporting requirements, as well as updating the requirements for eligibility with respect to certain changes of ownership.
- 2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are proposing to update the AKI payment rate for CY 2019. The proposed CY 2019 payment rate is \$235.82, which is the same as the base rate proposed under the ESRD PPS for CY 2019.

3. ESRD QIP

This proposed rule proposes a number of new requirements for the ESRD QIP beginning with PY 2021, including the following:

- We are proposing to update the ESRD QIP's measure removal criteria, which we now refer to as "factors", so that they are more closely aligned with the measure removal factors we have adopted, or proposed to adopt for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of the Meaningful Measures Initiative.
- We are proposing to remove four measures: Healthcare Personnel Influenza Vaccination, Pain Assessment and Follow-Up, Anemia Management, and Serum Phosphorus. Removal of these measures would align the ESRD QIP measure set more closely with the priorities we have adopted as part of our Meaningful Measures Initiative.
- We are proposing to make several changes to the domains and domain weights that we use for purposes of our scoring methodology to more closely align the ESRD QIP with the priorities we have adopted as part of our Meaningful Measures Initiative. We are proposing to remove the Reporting Domain from the Program and to move each reporting measure currently in that domain (and not being proposed for removal) to another domain that is better aligned with the focus area of that measure. Additionally, we are

proposing that the Patient and Family Engagement/Care Coordination Subdomain and the Clinical Care Subdomain, both of which are currently subdomains in the Clinical Measure Domain, would become their own domains. As a result, the ESRD QIP would be scored using four domains instead of three. Furthermore, we are proposing new domain and measure weights that better align with the priority areas we have adopted as part of our Meaningful Measures Initiative.

- We are proposing to update our policy governing when newly opened facilities must start reporting ESRD QIP data. The proposed policy would require facilities to begin reporting ESRD QIP data beginning with the month that begins 4 months after the month during which the CMS Certification Number (CCN) becomes effective (for example, a facility with a CCN effective date of January 15th would be required to begin reporting ESRD QIP data collected in May). The proposed policy would provide facilities with a longer time period than they are given now to learn how to properly report ESRD QIP data.
- We are proposing to increase the number of facilities that we select for validation under the National Healthcare Safety Network (NHSN) data validation study from 35 to 150 facilities, and to increase the number of records that each selected facility must submit to 20 records for each of the first 2 quarters of CY 2019 (for a total of 40 records). This proposal would improve the overall accuracy of the study.
- We are proposing to convert the current Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data validation study into a permanent program requirement using the methodology we first adopted for PY 2016 because an analysis demonstrated that this methodology produced reliable validation results. We are also proposing that the 10 point deduction for failure to comply with the data request, which was first adopted for PY 2017, would become a permanent program requirement.

This proposed rule also proposes a number of new requirements for the ESRD QIP beginning with PY 2022, including the following:

- We are proposing to adopt the Percentage of Prevalent Patients Waitlisted (PPPW) Measure and to place it in the proposed Care Coordination Measure Domain (NQF #2988).
- We are proposing to adopt the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988) and to place it in the Safety Measure Domain.

 We are proposing to increase the number of facilities that we select for validation under the NHSN data validation study from 150 to 300 facilities. This proposal would further improve the overall accuracy of the study.

This proposed rule also proposes to set forth new requirements for the ESRD QIP beginning with PY 2024, including

the following:

• We are proposing to adopt the Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure and to place it within the proposed Patient and Family Engagement/Care Coordination Domain as a second measure in the proposed Transplant measure topic.

Finally, we are proposing to codify in our regulations several previously finalized requirements for the ESRD QIP by revising § 413.177 and adopting a

new § 413.178.

4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): We are proposing to revise the DMEPOS CBP by implementing lead item pricing based on maximum winning bid amounts. We are proposing to revise the definition of bid to mean an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items. We are proposing to revise the definition of composite bid to mean the bid submitted by the supplier for the lead item in the product category. We are proposing to revise the definition of lead item to mean the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP: We are proposing transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in

the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: We are proposing to establish new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. We are also proposing to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: We are proposing to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Including the Northern Mariana
Islands in Future National Mail Order
CBPs: We intend to include the
Northern Mariana Islands under
national mail order competitive bidding
programs that become effective on or
after January 1, 2019, so we are
proposing to amend § 414.210(g)(7) to
indicate that beginning on or after the
date that contracts take effect for a
national mail order competitive bidding
program that includes the Northern
Mariana Islands, the fee schedule
adjustment methodology under this
paragraph would no longer apply.

C. Summary of Costs and Benefits

In section XVI of this proposed rule, we set forth a detailed analysis of the impacts that the proposed changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Proposed ESRD PPS

The impact chart in section XV of this proposed rule displays the estimated change in payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the proposed CY 2019

changes is projected to be a 1.7 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.8 percent increase in payments compared with freestanding facilities with an estimated 1.7 percent increase.

We estimate that the aggregate ESRD PPS expenditures would increase by approximately \$220 million in CY 2019 compared to CY 2018. This reflects a \$190 million increase from the payment rate update and a \$30 million increase due to the updates to the outlier threshold amounts. As a result of the projected 1.7 percent overall payment increase, we estimate that there would be an increase in beneficiary coinsurance payments of 1.7 percent in CY 2019, which translates to approximately \$60 million.

2. Impacts of the Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section XVI of this proposed rule displays the estimated change in proposed payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the proposed CY 2019 changes is projected to be a 1.5 percent increase in payments. Hospital-based ESRD facilities and freestanding facilities both have an estimated 1.5 percent increase in payments.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the proposed CY 2019 ESRD PPS base rate would increase by less than \$1 million in CY 2019 compared to CY 2018.

3. Impacts of the Proposed ESRD QIP

We estimate that the overall economic impact of the ESRD QIP would be approximately \$219 million in PY 2021. The \$219 million figure for PY 2021 includes costs associated with the collection of information requirements, which we estimate would be approximately \$181 million. For PY 2022, we estimate that ESRD facilities would experience an overall economic impact of approximately \$240 million as a result of the PY 2022 ESRD QIP. The \$240 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate would be approximately \$202 million. Our proposal to add the SWR measure to the ESRD QIP measure set in PY 2024 would not result in additional costs associated with the collection of information requirements because the measure does not use data reported to CROWNWeb.

- 4. Impacts of the Proposed Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules
- i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

This rule proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS Competitive Bidding Program. The impacts of the rule are estimated by rounding to the nearer 5 million dollars and are expected to cost \$10 million in Medicare benefit payments for the 5year period beginning January 1, 2019 and ending September 30, 2023. The impacts on beneficiary cost sharing is roughly \$3 million over this 5-year period. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be \$0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished in areas that are currently CBAs and in areas currently not CBAs on or after January 1, 2019. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018, which establish payment for items furnished in CBAs based on fee schedule amounts fully adjusted in accordance with current regulations at 42 CFR 414.210(g). The

impacts are expected to cost \$1,050 million dollars in Medicare benefit payments and \$260 million dollars in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be \$45 million dollars and \$30 million dollars, respectively. Section 503 of the Consolidated Appropriations Act of 2016 and section 5002 of the Cures Act, added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. We note that the costs for the Medicaid program and beneficiaries could be higher depending on how many state agencies adopt the higher Medicare adjusted fee schedule amounts for rural areas for use in paying claims under the Medicaid program. We are not able to quantify this impact.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This rule proposes to establish new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule proposes to establish new rules to address payment for certain ventilators that are subject to the payment rules at section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost \$15 million in Medicare benefit payments and \$0 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be \$0 million.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

This change would not have a fiscal impact.

II. Calendar Year (CY) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112-240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRDrelated drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized \$29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oralonly ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, pertreatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level

adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category (§ 413.234). The ESRD PPS functional categories represent distinct groupings of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. New injectable or intravenous products that are not included in a functional category in the ESRD PPS base rate are paid for using the TDAPA for a minimum of 2 years, until sufficient claims data for rate setting analysis are available. At that point, utilization would be reviewed and the ESRD PPS base rate modified, if appropriate, to account for these products. The TDAPA is based on pricing methodologies under section 1847A of the Act (§ 413.234(c)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 1, 2017, we published a final rule in the **Federal Register** titled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program" (82 FR 50738 through 50797) (hereinafter referred to as the CY 2018 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2018, the wage index, and the outlier policy, and pricing outlier drugs. For further detailed information regarding these updates, see 82 FR 50738.

B. Provisions of the Proposed Rule

1. Drug Designation Process

a. Protecting Access to Medicare Act of 2014

Section 217(c) of PAMA requires the Secretary to implement a drug designation process for: (1) Determining when a product is no longer an oralonly drug; and (2) including new injectable and intravenous products into the bundled payment under such system. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process that allows us to recognize when an oralonly renal dialysis service drug or biological is no longer oral only and a process to include new injectable and intravenous products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1)of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration (FDA). Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). As discussed in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022). effective January 1, 2016, if a new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or intravenous product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biologicals reflected in the base rate.

As we discuss in § 413.234(b)(2), if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the drug is evaluated. First, an existing EŠRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage. Next, the new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment (TDAPA). Then, the new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the TDAPA.

Under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. During the time a new injectable or intravenous product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate would be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

b. Renal Dialysis Drugs and Biologicals Reflected in the Base Rate (ESRD PPS Functional Categories)

As discussed above, in the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process as being dependent upon the functional

categories, consistent with our policy since the implementation of the PPS in 2011. We provide a detailed discussion (80 FR 69013 through 69015) on how we accounted for renal dialysis drugs and biologicals in the ESRD PPS base rate since its implementation on January 1, 2011. In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained that in order to identify drugs and biologicals that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biologicals billed on ESRD claims and evaluated each drug and biological to identify its category by indication or mode of action. Categorizing drugs and biologicals on the basis of drug action allows us to determine which categories (and therefore, the drugs and biologicals within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and intravenous drugs and biologicals into functional categories based on their action (80 FR 69014). This was done with the purpose of adding new drugs or biologicals with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals,

as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

Using the functional categorization approach, we established categories of drugs and biologicals that are not considered used for the treatment of ESRD, categories of drugs and biologicals that are always considered used for the treatment of ESRD, and categories of drugs and biologicals that may be used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). The drugs and biologicals that were identified as not used for the treatment of ESRD were not considered renal dialysis services and were not included in computing the base rate. The functional categories of drugs and biologicals that are not included in the base rate can be found in the CY 2011 ESRD PPS final rule (75 FR 49049). The functional categories of drugs and biologicals that were always and may be considered used for the treatment of ESRD were considered renal dialysis services and were included in computing the base rate. Subsequent to the CY 2011 discussion about the always and may be functional categories (75 FR 49050 through 49051), we also discussed these categories in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69018) and clarified the medical conditions or symptoms that indicate the drugs are used for the treatment of ESRD. See Table 1.

TABLE 1—ESRD PPS FUNCTIONAL CATEGORIES

| Category | Rationale for association |
|--|---|
| Access Management | Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement. |
| Anemia Management | Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron. |
| Bone and Mineral Metabolism | Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics. |
| Cellular Management | Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine. |
| Antiemetic | Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category. |
| Anti-infectives | Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs. |
| Antipruritic | Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis. |
| Anxiolytic | Drugs in this classification have multiple actions. Use within an ESRD functional category includes treatment of restless leg syndrome related to dialysis. |
| Excess Fluid Management | Drug/fluids used to treat fluid excess/overload. |
| Fluid and Electrolyte Management Including Volume Expanders. | Intravenous drugs/fluids used to treat fluid and electrolyte needs. |
| Pain Management | Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain. |

In computing the ESRD PPS base rate, we used the payments in 2007 for drugs and biologicals included in the *always* functional categories, that is, the injectable forms (previously covered under Part B) and oral or other forms of administration (previously covered under Part D) (75 FR 49050). For the oral or other forms of administration for those drugs that are always considered used for the treatment of ESRD, we determined that there were oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. Therefore, we included the payments made under Part D for oral vitamin D (calcitriol, doxercalciferol and paricalcitol) and oral levocarnitine in our computation of the base rate (75 FR 49042).

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49051), we explained that drugs and biologicals that may be used for the treatment of ESRD may also be commonly used to treat other conditions. We used the payments made under Part B in 2007 for these drugs in computing the ESRD PPS base rate, which only included payments made for the injectable version of the drugs. We excluded the Part D payments for the oral (or other form of administration) substitutes of the drugs and biologicals described above because they were not furnished or billed by ESRD facilities or furnished in conjunction with dialysis treatments (75 FR 49051). For those reasons, we presumed that these drugs and biologicals that were paid under Part D were prescribed for reasons other than for the treatment of ESRD. However, we noted that if these drugs and biologicals paid under Part D are furnished by an ESRD facility for the treatment of ESRD, they would be considered renal dialysis services and not be billed or paid under Part D.

Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) provides the Medicare allowable payments for all of the components of the ESRD PPS base rate for CY 2007, inflated to CY 2009, including payments for drugs and biologicals and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS has been delayed. A list of the specific Part B drugs and biologicals that were included in the final ESRD PPS base rate is located in Table C of the Appendix of the CY 2011 ESRD PPS final rule (75 FR 49205 through 49209). A list of the former Part D drugs that were included in the final ESRD PPS base rate is located in Table D of the Appendix of that rule (75 FR 49210). As discussed in section II.3.d of this proposed rule, the ESRD PPS base rate is updated annually by the ESRD bundled (ESRDB) market basket.

c. Section 1847A of the Social Security Act (the Act) and Average Sales Price (ASP) Methodology Under the ESRD PPS

In the CY 2005 Physician Fee Schedule (PFS) final rule, published on November 15, 2004 (69 FR 66299 through 66302) in the Federal Register, we discussed that section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1847A to the Act and established the Average Sales Price (ASP) methodology for certain drugs and biologicals not paid on a cost or prospective payment basis furnished on or after January 1, 2005. The ASP methodology is based on quarterly data submitted to CMS by drug manufacturers. The ASP amount is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of "best price" in the Medicaid drug rebate program. Each drug with a healthcare common procedure coding system (HCPCS) code has a separately calculated ASP. To allow time to submit and calculate these data, the ASP is updated with a two-quarter lag.1

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the ASP for the HCPCS code or 106 percent of the wholesale acquisition cost (WAC) of the HCPCS code.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases were the ASP is unavailable. Specifically Pub. 100–04, Chapter 17, section 20 (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/;clm104c17.pdf) titled "Payment Allowance Limit for Drugs and Biologicals Not Paid on a Cost or Prospective Payment Basis", provides guidance on how Medicare Part B pays for drugs and biologicals

under section 1847A of the Act and notes that, in the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—the wholesale acquisition cost; or the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals. This publication provides guidance on how Medicare Part B pays for drugs and biologicals under section 1847A of the Act.

In the CY 2018 ESRD PPS final rule (82 FR 50742 through 50743), we discussed how we have used the ASP methodology since the implementation of the ESRD PPS when pricing ESRDrelated drugs and biologicals previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations. We adopted § 413.234(c), which requires that the TDAPA is based on the pricing methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such pricing methodologies for new and existing injectable drugs or biologicals that qualify as an outlier service.

d. Proposed Revision to the Drug Designation Process Regulation

As noted above, in prior rulemakings we addressed how new drugs and biologicals are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biologicals in the ESRD PPS base rate since its implementation on January 1, 2011. Accordingly, the drug designation process we finalized is dependent upon the functional categories we developed and is consistent with the policy we have followed since the inception of the ESRD PPS. However, since PAMA only required the Secretary to establish a process for including new injectable and intravenous drugs and biologicals, such new products were the primary focus of the regulation we adopted at § 413.234, rather than codifying our full policy for other renal dialysis drugs, such as drugs and biologicals with other forms of administration, including, oral, that by law are included under the ESRD PPS (though oral-only renal dialysis drugs are required to remain outside of the ESRD PPS bundle until CY 2025).

In this proposed rule, we propose to revise the drug designation process regulations at § 413.234 to reflect that the process applies for all new renal

¹ Sheingold, S., Marchetti-Bowick, E., Nguyen, N., Yabrof, K.R. (2016, March). Medicare Part B Drugs: Pricing and Incentives. Retrieved from https:// aspe.hhs.gov/system/files/pdf/187581/ PartBDrug.pdf.

dialysis drugs and biologicals that are approved regardless of the form or route of administration, that is, new injectable, intravenous, oral, or other route of administration, or dosage form. We note that for purposes of the ESRD PPS drug designation process, use of the term form of administration is used interchangeably with route of administration. We are proposing these revisions so that the regulation reflects our long standing policy for all new renal dialysis drugs and biologicals, regardless of the form or route of administration, with the exception of oral-only drugs. Specifically, we propose to replace the definition of "new injectable or intravenous product" at § 413.234(a), "an injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition(s) associated with ESRD," with a definition for "new renal dialysis drug or biological," to encompass the broader scope of the drug designation process. Under this definition, a new renal dialysis drug or biological "must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs or biologicals are excluded until January 1, 2025.

In our proposal to replace the definition of "new injectable or intravenous product" in § 413.234(a) with the proposed definition of "new renal dialysis drug or biological," we have included the clause, "have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures." We note that this would be a change from the existing policy of requiring that the new product be assigned an HCPCS code. We are proposing that new renal dialysis injectable or intravenous products are no longer required to be assigned an HCPCS code before the TDAPA can apply, instead we would require that an application has been submitted in accordance with the Level II HCPCS coding procedures. This would allow the application of the TDAPA to the ESRD PPS base rate to happen more quickly than under our current process wherein a lag that occurs when a drug or biological is approved but is waiting for the issuance of a code. Information regarding the HCPCS process is

available on the CMS website at https://www.cms.gov/Medicare/;Coding/MedHCPCSGenInfo/Application_Form_and Instructions.html.

This proposed definition would also address prior concerns that we narrowly defined "new" in the context of the functional categories (that is, the drug designation process primarily addresses "new" drugs that fall outside of the functional categories for purposes of being newly categorized and eligible for the TDAPA). As noted in section II.B.1.f of this proposed rule, even though we are maintaining the functional categories to determine whether or not to potentially adjust or modify the ESRD PPS base rate (that is, those renal dialysis drugs and biologicals that do not fall within an existing category), we are proposing to expand the TDAPA policy based on whether the renal dialysis drug or biological is new, that is, any renal dialysis drug or biological newly approved on or after January 1,

We solicit comment on the proposed revisions to $\S 413.234(a)$, (b), and (c).

e. Basis for Expansion of the TDAPA Eligibility Criteria

In the CY 2016 ESRD PPS final rule (80 FR 69017 through 69024), we acknowledged that there are unique situations identified by the commenters during that rulemaking regarding the eligibility criteria for the TDAPA. For example, commenters stated that they believed the drug designation process was excessive, could hinder innovation, prevent new treatment options from entering the marketplace, and CMS should contemplate the cost of new drugs and biologicals that fall within the functional categories. In the following paragraphs we have summarized key concerns commenters have raised. We indicated in the CY 2016 ESRD PPS final rule that we anticipated addressing these situations in future rulemaking and stated that we planned to consider the issues of ESRD facility resource use, supporting novel therapies, and balancing the risk of including new drugs for both CMS and the dialysis facilities.

In the CY 2016 ESRD PPS final rule (80 FR 69017 through 69024), commenters seemed concerned about the cost of new drugs that fit into the functional categories, rather than the process of adding new drugs to existing categories.

In the CY 2016 ESRD PPS final rule (80 FR 69020), a drug manufacturer suggested that in order to promote access to new therapies and encourage innovation in ESRD care, the TDAPA should apply to all new drugs not just

those drugs that are used to treat or manage a condition for which we have not adopted a functional category. They pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. They indicated that under the proposed approach, CMS would make no additional payment regardless of whether the drug has a novel mechanism of action, new FDA approval, or other distinguishing characteristics and argued that such distinguishing characteristics provided rationale for additional payment. The commenter believed the CMS proposal sent conflicting messages to manufacturers about the importance of developing new treatments for this underserved patient population.

An organization of home dialysis patients commented (80 FR 69022) with a similar concern, noting that the functional categories are too broad and could prevent people on dialysis from receiving needed care, and be detrimental to innovation. The commenter stated that in the future there could be a new medication to help with fluid management but patients would be shut out of ever having the option for a new fluid management therapy since there is an existing functional category for excess fluid management and therefore, these drugs are considered to be included in the base rate. Therefore, we believe the commenter meant that drug manufacturers would be less likely to develop a new fluid management drug knowing it would never qualify for additional payment under the ESRD PPS. The commenter asked that CMS provide additional payment for new drugs that fit into the functional categories in order to incentivize new medications to come to market and to ensure they have the opportunity for better care, choices and treatment.

A national dialysis patient advocacy organization explained (80 FR 69021) that if new products are immediately added to the bundle without additional payment it would curtail innovation in treatments for people on dialysis. They believed clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes, and that the proposed rule did not allow for this. The commenter explained that Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines are often updated when evidence of improved therapies on patient outcomes are made available and that this rigorous and evidence-based process is extremely important in guiding widespread

treatment decisions in nephrology. The commenter expressed concern that under the proposed rule, reimbursement and contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated.

The comments we received for the drug designation process in the CY 2016 ESRD PPS rulemaking (80 FR 69017 through 69024) indicated that commenters were also concerned about the cost of the new drugs and biologicals, and in particular, new drugs and biologicals that fall within the functional categories, and therefore, considered by CMS to be reflected in the ESRD PPS base rate.

A national dialysis organization strongly urged (80 FR 69017) CMS to adopt the same process for all new drugs and biologicals (as opposed to only those that do not fall within a functional category) unless they are substantially the same as drugs or biologicals currently paid for under the ESRD PPS payment rate. For new drugs or biologicals that are substantially the same as drugs or biologicals currently paid under the ESRD PPS, the organization supported incorporating them into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the transition period if it can be shown that the PPS rate is adequate to cover the cost of the drug or biological. The organization believed if the rate is inadequate to cover the cost of the new drug then the TDAPA should apply. An LDO stated that, if implemented, the proposed process could jeopardize patient access to drugs that are clinically superior to existing drugs in the same functional category. For example, the commenter stated, if a new substantially more expensive anemia management drug is released and is clinically proven to be more effective than the current standard of care under the proposed rule, the ESRD PPS base rate would remain stagnant. They continued that it is not reasonable for CMS to expect that all dialysis facilities would incur frequent and substantial losses in order to furnish the more expensive, albeit more clinically effective, drug.

A dialysis organization and a professional association asked (80 FR 69019) that CMS consider a pass-through payment, meaning Medicare payment in addition to the ESRD PPS base rate for all new drugs that are considered truly new. They recommended a rate of 106 percent of ASP, minus the portion of the ESRD PPS base rate that CMS determines is attributable to the category of drugs that corresponds to a truly new drug. An

LDO stated (80 FR 69020) that defining new drugs requires special consideration of cost. They suggested a similar approach by stating that rather than comparing the cost of the new drug to the ESRD PPS base rate, we should compare it to the cost of the existing drugs in the same CMS-defined "mode of action" category. In such a case, a drug might qualify for payment of the TDAPA on the basis that its cost per unit or dosage exceeds a specified percentage (for example 150 percent) of the average cost per unit or dosage of the top three most common drugs in the same category (based on utilization data). This comparison would demonstrate that the amount allocated to that category in the ESRD PPS base rate is insufficient to cover the cost of the new drug.

Other commenters referred (80 FR 69020) to pathways in other payment systems that provide payment for new drugs and biologicals to account for their associated costs. For example, the Outpatient Prospective Payment System (OPPS) provides a pass-through payment and the Inpatient Prospective Payment System (IPPS) provides a new technology add-on payment. Commenters indicated (80 FR 69020) that we should decouple the TDAPA from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biologicals and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS.

f. Proposed Expansion of the TDAPA Eligibility Criteria

We continue to believe that the drug designation process does not prevent ESRD facilities from furnishing available medically necessary drugs and biologicals to ESRD beneficiaries. Additionally, our position has been that payment is adequate to ESRD facilities to furnish new drugs and biologicals that fall within existing ESRD PPS functional categories. The per treatment payment amount is a patient and facility level adjusted base rate plus any applicable adjustments, such as training or outlier. Finally, the ESRD PPS includes the ESRDB market basket, which updates the PPS base rate annually for input price changes for providing renal dialysis services and accounts for price changes of the drugs and biologicals that are reflected in the ESRD PPS base rate (80 FR 69019). However, in the CY 2016 ESRD PPS final rule, we also acknowledged that the outlier policy would not fully cover the cost of furnishing a new drug (80 FR 69021) and that newer drugs may be more costly. Consequently, due to the

reasons detailed in the following paragraphs, we are reconsidering our previous policy on the drug designation policy.

We recognize the unique situations identified by the commenters discussed in section II.B.1.e of this proposed rule, and how they are impacted by the eligibility criteria for the TDAPA. Concerns regarding inadequate payment for renal dialysis services and hindrance of high-value innovation, among others, are important issues that we contemplate while determining appropriate payment policies. Additionally, subsequent to the issuance of the CY 2016 ESRD PPS final rule, we continue to hear concerns that the drug designation process is restrictive in nature; and receive requests from the dialysis industry and stakeholders that we reconsider the applicability of the TDAPA.

We acknowledge that ESRD facilities have unique circumstances with regard to implementing new drugs and biologicals into their standards of care. For example, when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies into their care plans. Newly launched drugs and biologicals can be unpredictable with regard to their uptake and pricing which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We agree that this uptake period would be best supported by the TDAPA pathway because it would help facilities transition/test new drugs and biologicals in their businesses under the ESRD PPS. The TDAPA provides flexibility and targets payment for the use of new renal dialysis drugs and biologicals during the period when a product is new to the market so that we can evaluate if resource use can be aligned with payment. As explained in section II.B.1.b of this proposed rule, the ESRD PPS base rate includes dollars allocated for drugs and biologicals that fall within a functional category, but those dollars may not directly address the total resource use associated with the newly launched drugs trying to compete in the renal dialysis market.

We believe that we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biologicals that, while are already accessible to them, may be under-prescribed because the new drugs are priced higher than currently utilized drugs (as argued by commenters).

Therefore, beginning January 1, 2019, we are proposing to add § 413.234(b)(1)(i), (ii) and revise § 413.234(c) to reflect that the TDAPA, under the authority of section 1881(b)(14)(D)(iv) of the Act, would apply to all new renal dialysis injectable or intravenous products, oral equivalents, and other forms of administration drugs and biologicals, regardless of whether or not they fall within a functional category. New renal dialysis drugs and biologicals that do not fall within an existing functional category would continue to be paid under the TDAPA and the ESRD PPS base rate would be modified, if appropriate, to reflect the new functional category. We are revising § 413.234(b)(2)(ii) and § 413.234(c)(2), removing § 413.234(c)(3), and adding § 413.234(c)(2)(i) to reflect that we would continue to provide the TDAPA, collect sufficient data, and modify the ESRD PPS base rate, if appropriate, for these new drugs and biologicals that do not fall within an existing functional

We propose to revise § 413.234(c)(1) to reflect that for new renal dialysis drugs and biologicals that fall within a functional category, the TDAPA would apply for only 2 years. While we are not collecting claims data for purposes of analyzing utilization to result in a change to the base rate, we would still monitor renal dialysis service utilization for trends and believe that this timeframe is adequate for payment. We believe that 2 years is a sufficient timeframe for facilities to set up system modifications, and adjust business practices so that there is seamless access to these new drugs within the ESRD PPS base rate. In addition, when we implement policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We believe that this 2-year timeframe is similar in that facilities are making changes to their systems and care plan to incorporate the new renal dialysis drugs and biologicals into their standards of care and this could be supported by a transition period. Also, the TDAPA for 2 years would address the stakeholders concerns regarding additional payment to account for higher cost of more innovative drugs that perhaps may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this transitional payment would give the new renal dialysis drugs and biologicals a foothold in the market so that when the timeframe is complete, they are able to compete with the existing drugs and biologicals under the

outlier policy, if applicable. Meaning, once the timeframe is complete, drugs would then qualify as outlier services, if applicable, and the facility would no longer receive the TDAPA for any one particular drug. Instead, in the outlier policy space, there is a level playing field where drugs could gain market share by offering the best practicable combination of price and quality. We believe that the proposed timeframe is long enough to be meaningful but not too long as to improperly incentivize high cost items without more value, for example, substitutions of those drugs that already exist in the functional

category.

We note that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary cost sharing, since we have not previously provided the TDAPA for new renal dialysis drugs and biologicals in the past. It is our understanding that there are new drugs and biologicals in the pipelines, for example, we are aware that there are new drugs that would fall within the anemia management, bone and mineral, and pain management categories. We would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biologicals that qualify. We would address any concerns through future refinements to the TDAPA policy.

We are also proposing that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period we would not modify the ESRD PPS base rate, but at the end of the 2 years, as consistent with the existing outlier policy, the drug would be eligible for outlier payment. However, as discussed in section II.B.1.h of this proposed rule, if the new renal dialysis drug or biological is considered to be a composite rate drug, it would not be eligible for an outlier payment. The intent of the TDAPA for these drugs is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new drug. We do not believe that it would be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biologicals that fall within existing functional categories and that doing such would be in conflict with the fundamental principles of a PPS. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's cost which creates an incentive for cost control. It is not the intent of a PPS to

add dollars to the base whenever something new is made available. We believe this proposal, that is, no modification to the base rate at the end of the TDAPA period for new renal dialysis drugs and biologicals that fall within an existing functional category would maintain the overall goal of a bundled PPS, that is, the limitation of applying the TDAPA would not undermine the bundle since there is no permanent adjustment to the base rate. This proposal would also strike a balance of maintaining the existing functional category scheme of the drug designation process and not adding dollars to the ESRD PPS base rate when the base rate may already reflect costs associated with such services, while still promoting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment. We are proposing to add § 413.234(c)(1)(i) to reflect that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period, we would not modify the ESRD PPS base rate. We solicit comment on this proposal.

We are proposing to operationalize this proposed policy no later than January 1, 2020. This deadline would provide us with the appropriate time to prepare the necessary changes to our

claims processing systems.

We solicit comment on the proposal to revise § 413.234(c) and (c)(1) to reflect that the TDAPA would apply for all new renal dialysis drugs and biologicals regardless of whether they fall within a functional category. Then, for new renal dialysis drug or biological that falls within an existing functional category, that payment would apply for 2 years and there would be no modification to the ESRD PPS base rate. We are also soliciting comment on the appropriateness of the 2-year timeframe for the TDAPA for new renal dialysis drugs and biologicals that fall within existing functional categories.

g. Proposed Basis of Payment for the TDAPA

Currently, under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act, including 106 percent of ASP (ASP+6). If we adopt the proposals discussed in section II.B.1.f of this proposed rule using the same pricing methodologies, Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we have not previously provided the TDAPA for all new renal dialysis drugs and biologicals in the past.

The TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biologicals under Medicare Part B, and under section 1881(b)(14)(D)(iv) of the Act, we believe it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies. For this proposed rule, we considered options for basing payment under the TDAPA, for example, maintaining the policy as is and facility cost of acquiring drugs and biologicals. We found that the while ASP could encourage certain unintended consequences (discussed below), it continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and, as described in section II.B.1.c, is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.

Further, since the implementation of section 1847A of the Act, stakeholders and executive policy advisors have analyzed this section of the statute and issued their respective critiques on the purpose of the ASP add-on percentage. On March 8, 2016, the Assistant Secretary for Planning and Evaluation (ASPE) issued an Issue Brief titled, "Medicare Part B Drugs: Pricing and Incentives" (https://aspe.hhs.gov/ system/files/pdf/;187581/ *PartBDrug.pdf*). In this brief ASPE touches on several concerns they have about the ASP methodology. Two of those concerns regard the economic incentives of cost and value. ASPE noted that the ASP methodology for Part B drugs falls short of providing value based incentives in several ways. Specifically, they noted physicians can often choose between several similar drugs for treating a patient and although the current system may encourage providers and suppliers to pursue the lowest price for drugs that are multiple source, payment based on drug specific ASP provides little incentive to make choices among the therapeutic options with an eye towards value and choose among the lowest price among all drugs available to effectively treat a patient. Rationale for the 6 percent add-on has been to cover administrative and overhead costs, but such costs are not proportional to the price of the drug. The fixed 6 percent of ASP provides a larger "add-on" for higher priced drugs than for lower priced drugs, resulting in increased profit margins for the physicians' office and hospitals creating a perverse incentive to choose the high

priced drugs as opposed to lower priced alternatives of similar effectiveness.

In MedPAC's June 2015 Report to Congress (http://medpac.gov/docs/ default-source/reports/june-2015-reportto-the-congress-medicare-and-thehealth-care-delivery-system.pdf), MedPAC provides discussion around the meaning of the 6 percent that is added to the ASP and provides their opinion on its purpose. In their report, they state "There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent is intended to cover drug storage and handling costs. Others contend that the 6 percent is intended to maintain access to drugs for smaller practices and other purchasers who may pay above average prices for the drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (for example, promptpay discounts). Another rationale for the percentage add-on may be to provide protection for providers when price increases occur and the payment rate has not yet caught up.'

Finally, with regard to acquisition costs in a 2006 Report to Congress titled, "Sales of Drugs and Biologicals to Large Volume Producers (https:// www.cms.gov/Research-Statistics-Dataand-Systems/;Statistics-Trends-and-Reports/Reports/Downloads/LVP RTC 2 09 06.pdf), the Secretary was tasked to submit a Report to Congress (RTC) to include recommendations as to whether sales to large volume purchasers should be excluded from the computation of manufacturer's ASP. The contractor made extensive efforts to collect and analyze data regarding large volume drug purchasers. They were unable to obtain data on ASP by type of purchaser from the drug manufacturers, and were unable to determine net acquisition costs. The sensitive and proprietary nature of prescription drug pricing data made it extremely difficult to obtain the data necessary for the report. Given that ASP was designed to broadly reflect market prices without data on net acquisition cost, it is not possible to accurately analyze the impact of large volume purchasers on overall ASP. In 2018, we remain unable to obtain contractual information regarding drug pricing and ESRD PPS, which is especially pertinent since the dialysis stage is dominated by two large dialysis organizations who administer drugs and biologicals to the majority of ESRD beneficiaries.

To balance the price controls inherent in any PPS we believe that we need to take all of these issues into consideration to revise the basis for TDAPA payment. We are, and will continue to be, conscious of ESRD facility resource use and recognize the financial barriers that may be preventing uptake of innovative new drugs and biologicals. Therefore, we are proposing to revise § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we would base the TDAPA payments on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6).

This proposal applies to new renal dialysis drugs and biologicals that fall within an existing functional category and to those that do not fall within an existing functional category. We believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biologicals that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biologicals that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biologicals. We note that there is no clear statement from Congress as to why the payment allowance is required to be 106 percent of ASP (ASP+6) as opposed to any other value from 101 to 105 percent, and, as MedPAC discussed in their June 2015 report, there is no consensus amongst stakeholders.

We further believe that moving from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0 for all new renal dialysis drugs and biologicals regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary coinsurance) and stakeholder concerns discussed in section II.B.1.e of this proposed rule. That is, we propose to provide the TDAPA for new drugs that are within an existing functional category, which is an expansion from the existing policy. This proposal would also aim to promote innovation and bring more high-value drugs to market. This proposal would further address concerns about incentivizing use of high cost drugs in ESRD facilities, also discussed in section II.B.1.e of this proposed rule. We solicit comment on the proposal to revise § 413.234(c) to reflect that we would base the TDAPA payments on ASP+0. While we propose to change the basis of payment for the TDAPA from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0, we are also soliciting comment on other add-on percentages to the ASP amount, that is, ASP+1 to 6 percent for commenters to explain why it may be appropriate to have a higher percentage.

There are times when the ASP is not available. For example, when a new drug or biological is brought to the market, sales data is not sufficiently available for the manufacturer to compute an ASP. Therefore, when the ASP is not available, we propose that the TDAPA payment would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA payment would be based on the drug manufacturer's invoice. We solicit comment on this proposal.

We note that this proposal to use ASP+0 as the basis for the TDAPA payments, if adopted, would apply prospectively to new drugs and biologicals as of January 1, 2019. Currently, calcimimetics are eligible for the TDAPA and payment for both the injectable and oral versions are based on pricing methodologies under section 1847A of the Act. This proposal would not affect calcimimetics, which would continue to be eligible for the TDAPA payment based on ASP+6.

h. Drug Designation Process for Composite Rate Drugs and Biologicals

In the CY 2016 ESRD PPS final rule. we did not discuss composite rate drugs and biologicals explicitly in context of the drug designation process. Composite rate services are discussed in the CY 2011 ESRD PPS final rule (75 FR 49036. 49078 through 49079) and are identified as renal dialysis services in § 413.171 and under section 1847(b)(14)(B) of the Act. Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and not billed separately. Composite rate drug and biological policies are discussed in Pub. 100-02, chapter 11, section 20.3.F (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ downloads/bp102c11.pdf). This manual lists the drugs and fluids considered in the composite rate as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl,

hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the ESRD PPS.

We used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified on Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as "Composite Rate Services". In addition, we note that under § 413.237, composite rate drugs and biologicals are not permitted to be considered for an outlier payment. The outlier policy is discussed in section II.B.3.c of this proposed rule.

Composite rate drugs and biologicals were also grouped into functional categories during the drug categorization for the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053). For example, heparin is a composite rate drug and falls within the Access Management category. However, these functional categories exclude certain composite rate items given that certain drugs and biologicals formerly paid for under the composite rate were those that were routinely given during the time of the patient's dialysis and not always specifically for the treatment of their ESRD. For example, an antihypertensive composite rate drug that falls within the Cardiac Management category, which is not an ESRD PPS functional category, is not considered to be furnished for the treatment of ESRD and therefore, not included under the ESRD PPS.

In light of our proposal to expand the drug designation process and the TDAPA, we also propose, under the authority of section 1881(b)(14)(D)(iv) of the Act, that it extend to composite rate drugs and biologicals that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2019, we propose that if a new renal dialysis drug or biological as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We note that composite rate drugs and biologicals that are not considered to be furnished for the treatment of ESRD, and therefore, are not included in the ESRD PPS, would not be eligible for the TDAPA, for example, antihypertensives. We believe that the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may

not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. Accordingly, we propose that the expanded drug designation process and the TDAPA policy we proposed in section II.B.1.f of this proposed rule, including the proposed changes to § 413.234, would be applicable to composite rate drugs, with one exception. Under our proposal, new composite rate drugs would not be subject to outlier payments following the period that the TDAPA applies, since we are not proposing to change the current outlier policy under § 413.237, which does not apply to composite rate drugs. We are, however, soliciting comments on whether we should consider applying our outlier policy to composite rate drugs in the future (see section II.B.3.c of this proposed rule). We would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biologicals that qualify. We would address any concerns through future refinements to the TDAPA policy.

We solicit comment on the proposal to recognize composite rate drugs and biologicals in the same manner as drugs that were formerly separately paid under Part B when furnished for the treatment of ESRD for purposes of the proposed revisions to the drug designation process and eligibility for the TDAPA.

2. Low-Volume Payment Adjustment (LVPA) Revision

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities furnishing such services. We have established a low-volume payment adjustment (LVPA) factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, "treatments" means total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare as well as ESRD and non-ESRD). For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 HD treatments. As noted, we base eligibility on the 3 years preceding the payment year and those years are based on cost reporting periods. Specifically, under § 413.232(g), the ESRD facility's cost reports for the periods ending in the 3 years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified § 413.232 and qualifies as a low-volume ESRD facility. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions. This timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, CMS Pub. 100-02, Chapter 11, section 60.B.1.

b. Revisions to the LVPA Requirements and Regulations

We have heard from stakeholders that low-volume facilities rely on the lowvolume adjustment and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances. For example, in the CY 2017 ESRD PPS final rule (81 FR 77863), a commenter suggested refinements to the definition of a low-volume facility to address the rare change of ownership (CHOW) instance wherein the new owner accepts the Medicare agreement but the ownership change results in a new provider number because of a facility's type reclassification. The commenter

explained that in this example, due to the issuance of a new Medicare provider billing number or provider transaction access number (PTAN) when the facility's type is reclassified, this facility would be deemed ineligible for the LVPA since our policy requires new Medicare provider billing numbers qualify for the LVPA, which takes 3 years. We also discovered that facilities that change their fiscal year without going through a CHOW become ineligible for the adjustment. Finally, stakeholders also communicated that the strict enforcement of the attestation deadline without exception should be reevaluated since missing the deadline results in the facility losing the LVPA and their payments are significantly reduced. Thus, in order to be responsive to stakeholders and increase flexibility with regard to eligibility for the LVPA, we are proposing to make changes to the LVPA regulation at § 413.232.

The first proposed revision concerns the assignment of a PTAN when a facility undergoes a CHOW as described in 42 CFR 489.18. A facility is ineligible under § 413.232(b)(2) and (g)(2) for the LVPA for 3 years if it goes through a CHOW that results in a new PTAN. In response to a comment we received during the CY 2011 ESRD PPS rulemaking (75 FR 49123), we explained that we believe that a 3-year waiting period serves as a safeguard against facilities establishing new facilities that are purposefully small. We also explained that we structured our analysis of the ESRD PPS by looking across data for 3 years as we believe that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

However, as we mentioned above, we have heard from stakeholders that this policy unfairly impacts facilities that undergo a CHOW that results in a change in facility type (for example, the facility type changes from hospitalbased to freestanding). Under this scenario, as discussed in the Medicare State Operations Manual, Pub. 100-07, Chapter 3, Section 3210.4C (https:// www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ downloads/som107c03.pdf) and the Medicare Program Integrity Manual, Pub. 100-08, Chapter 15, Section 15.7.7.1 (https://www.cms.gov/ Regulations-and-Guidance/Guidance/ Manuals/Downloads/pim83c15.pdf), CMS requires the issuance of a new CMS Certification Number (CCN) and provider agreement, which may lead to the issuance of a new PTAN, even if the new owner has accepted assignment of the existing Medicare provider agreement, that is, the new owner

accepts the previous owner's assets and liabilities.

We agree with the stakeholders that the language in the regulation regarding PTAN status could restrict LVPA eligibility to an otherwise qualified ESRD facility from receiving the adjustment for 3 years, until the new PTAN qualifies for the adjustment. We recognize that there are technicalities regarding the assignment of a PTAN that could cause substantive impacts with eligibility for the LVPA that were not contemplated at the time the regulation was established. The intent of the LVPA has always been that if an ESRD facility undergoes a CHOW wherein the new owner accepts assignment of the existing Medicare provider agreement that they should continue to be eligible for the LVPA since this indicates a consistency in business operations.

We are proposing to expand the definition of a low-volume facility in § 413.232(b)(2) to include CHOWs where the new owner accepts assignment of the existing Medicare provider agreement and a new PTAN is issued due to a change in facility type. This proposal does not extend to CHOWs where a new PTAN is issued for any other reason. We solicit comment on the proposal to revise the language at § 413.232(b)(2) to reflect that ESRD facilities can meet the definition of a low-volume facility when they have a CHOW that results in a new PTAN due to a change in facility type but accepts assignment of the existing Medicare provider agreement. We are also proposing to amend § 413.232(g)(2), which governs the determination of LVPA eligibility, to recognize the proposed expansion of the low-volume facility definition to allow for PTAN changes when the facility type changes as a result of CHOW. We solicit comment on this proposal.

We are also proposing to allow for an extraordinary circumstance exception to the November 1 attestation deadline under § 413.232(e). We agree with the stakeholders that there could be unforeseeable factors that contribute to a delay in the submission of the attestation and we would not want to prevent an otherwise qualified ESRD facility from receiving the adjustment. For example, while a failure to timely submit the attestation because of poor communication between a facility and its respective MAC, or because a facility forgets to send the attestation to the MAC, would not constitute extraordinary circumstances; a natural disaster could, because such an event is unforeseeable and extraordinary, which may understandably delay the timely submission of the attestation. We expect

extraordinary exceptions to be rare and the determination of acceptability would be made on a case-by-case basis. We have heard from stakeholders that they have lost eligibility for the LVPA due to extraordinary circumstances, such as natural disasters, that prevented them from submitting their attestation by the deadline. In those types of instances, we believe an exception to the attestation deadline could be warranted. Therefore, we are proposing to add a clause in § 413.232(e) to recognize an exception to the filing deadline for extraordinary circumstances. In order to request an extraordinary circumstance exception, we also propose that the facility would need to submit a narrative explaining the rationale for the exception to their MAC. We would evaluate and review the narrative to determine if an exception is justified, and such a determination would be final, with no appeal. We solicit comment on the proposal to revise the language at § 413.232(e) to reflect that CMS would allow an exception to the attestation deadline of November 1 for extraordinary circumstances, if determined appropriate.

In addition, we are also proposing to allow ESRD facilities that change their fiscal year-end for cost reporting purposes outside of a CHOW to qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. Under § 413.24(f)(3), facilities are able to change their cost reporting period when they request a change in writing from their MAC and meet specific criteria for approval. However, the current LVPA regulation at § 413.232(g)(2)(ii) does not technically address requirements for changing cost reporting periods except as a result of a CHOW, which has prohibited facilities from receiving the LVPA if they make a business decision to adjust their cost reporting period, which could interfere with the normal course of business. We recognize that there are business decisions an ESRD facility could make with regard to cost reporting periods that could substantively impact eligibility for the LVPA that we did not contemplate at the time the regulation was adopted. Specifically, there could be reasons why a cost report does not span 12consecutive months. We did not intend for an ESRD facility to lose their LVPA eligibility simply because they made a decision to change their cost reporting period. The requirement that cost reports span 12-consecutive months was to bring a measure of consistent business operations.

We are proposing to add a new paragraph (3) to § 413.232(g) to provide

direction for MACs in verifying the number of treatments when a change in a cost reporting period is approved. When this occurs, we propose that MACs would combine the two nonstandard cost reporting periods of less than 12 months to equal a full 12consecutive month period or combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. This proposal does not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3). We solicit comment on the proposal to add proposed § 413.232(g)(3) to change the information and cost report timeframes MACs would review to determine LVPA eligibility. This would apply to ESRD facilities that change their cost reporting year for purposes outside of a CHOW to qualify for the LVPA, provided they otherwise meet the LVPA eligibility criteria for the purposes of allowing the ESRD facility to continue to receive the adjustment.

Finally, we are proposing two additional changes to correct and further clarify the LVPA regulation. The first would correct a cross-reference in § 413.232(b) by changing "paragraph (h)" to "paragraph (g)". This error is the result of prior changes we made to the regulation when we deleted other paragraphs, but did not update the reference accordingly. The second proposed revision, which we are making to § 413.232(c)(2), would clarify that the reference to miles, are road miles. CMS recognizes that the current designation of miles under the regulation may not be specific enough and could cause confusion, and we have issued guidance (Medicare Benefit Policy Manual, Pub. L. 100-02. Chapter 11. Section 60) addressing road miles. Accordingly, we are proposing clarifying edits to § 413.232(c)(2).

- 3. Proposed CY 2019 ESRD PPS Update a. ESRD Bundled (ESRDB) Market Basket and Labor-Related Share
- i. Proposed Rebasing of the ESRDB Market Basket

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase

factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). Effective for CY 2019, we are proposing to rebase the ESRDB market basket to a base year of CY 2016.

Although "market basket" technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term "ESRDB market basket," as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index is constructed in three steps. First, a base period is selected (in this proposed rule, we are proposing to use 2016 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called "cost weights" or "expenditure weights." Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a "price proxy". In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time.

Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services purchased to provide ESRD services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an ESRD facility hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility, but would not be factored into the price change measured by a fixed-weight ESRD market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We are proposing to use CY 2016 as the base year for the proposed rebased ESRDB market basket cost weights. The cost weights for this proposed ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2016 (that is, the average index level for CY 2016 is equal to 100). The major source data for the proposed ESRDB market basket is the 2016 Medicare cost reports (MCRs) (Form CMS-265-11), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2016 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also are proposing to use May 2016 Bureau of Labor Statistics (BLS) Occupational Employment Statistics data to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our methodology below.

The terms "rebasing" and "revising," while often used interchangeably, actually denote different activities. The term "rebasing" means moving the base year for the structure of costs of an input price index (that is, in this exercise, we

are proposing to move the base year cost structure from CY 2012 to CY 2016) without making any other major changes to the methodology. The term "revising" means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2019, we are proposing to rebase the ESRD market basket to reflect the 2016 cost structure of ESRD facilities. We are not proposing to revise the index; that is, we are not proposing to make any changes to the cost categories or price proxies used in the index.

We selected CY 2016 as the new base year because 2016 is the most recent year for which relatively complete MCR data are available. In developing the proposed market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265-11) for 2016 for each freestanding ESRD facility that reported expenses and payments. The 2016 MCRs are those ESRD facilities whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 MCRs, approximately 88 percent of freestanding ESRD facilities had a begin date on January 1, 2016, approximately 6 percent had a begin date prior to January 1, 2016, and approximately 6 percent had a begin date after January 1, 2016. Using this methodology allowed our sample to include ESRDs with varying cost report years including, but not limited to, the federal fiscal or CY.

We propose to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities) because freestanding ESRD data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for a hospital-based ESRD reflect the allocation of overhead from the entire institution.

We developed cost category weights for the proposed 2016-based ESRDB market basket in two stages. First, we derived base year cost weights for nine major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Machinery) from the ESRD MCRs. Second, we are proposing to divide the Administrative and General cost category into further detail using 2012 U.S. Census Bureau Services Annual Survey (SAS) data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2016 levels. We apply the estimated 2016 distributions from the SAS data to the 2016 Administrative and General cost weight to yield the

more detailed 2016 cost weights in the proposed market basket. This is similar to the methodology we used to break the Administrative and General costs into more detail for the 2012-based ESRDB market basket (79 FR 40217 through 40221). The only difference is that for this proposed rebasing because SAS data is not available after 2012 we inflated the 2012 expense levels to 2016 dollars using appropriate price proxies and applied this expense distribution to the Administrative and General cost weight for 2016.

We are proposing to include a total of 20 detailed cost categories for the proposed 2016-based ESRDB market basket, which is the same number of cost categories as the 2012-based ESRDB market basket. We are proposing to continue to assume that 87 percent of Professional Fees and 46 percent of capital costs are labor-related costs and would be included in the proposed labor-related share. A more thorough discussion of our proposals is provided below.

a. Cost Category Weights

Using Worksheets A and B from the 2016 MCRs, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Equipment, and Capital-Related Machinery. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs reimbursable under the ESRD bundled payment system. For example, we excluded expenses related to vaccine costs from total expenditures since these are not reimbursable under the ESRD bundled payment.

In order to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories for each cost category, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The proposed data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included information from approximately 5,700 independent ESRD facilities' cost reports from an available pool of 6,410 cost reports.

Table 2 presents the proposed 2016based ESRDB and 2012-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 2—PROPOSED 2016-BASED ESRDB MARKET BASKET MAJOR COST WEIGHTS DERIVED FROM THE MEDICARE COST REPORT DATA

| Cost category | Proposed 2016-based ESRDB market basket (percent) | 2012-based ESRDB market basket (percent) |
|--|---|---|
| Wages and Salaries | 32.6 | 31.8 |
| Employee Benefits | 7.0 | 6.6 |
| Pharmaceuticals | 12.4 | 16.5 |
| Supplies | 10.4 | 10.1 |
| Lab Services | 2.2 | 1.5 |
| Housekeeping and Operations | 3.9 | 3.8 |
| Administrative and General | 18.4 | 17.4 |
| Capital-related Building and Fixed Equipment | 9.2 | 8.4 |
| Capital-related Machinery | 3.8 | 3.9 |

Note: Totals may not sum to 100.0 percent due to rounding.

We are proposing to disaggregate certain major cost categories developed from the MCRs into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were modified to yield the proposed 2016 ESRDB market basket expenditure categories and weights presented in this proposed rule.

Wages and Salaries

The proposed Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2016 was derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we are proposing to derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the MCR. The estimated ratios were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct cost centers: 'Operations and Maintenance' combined with 'Machinery & Rental & Maintenance' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W)

Benefits for Direct Patient Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Pharmaceuticals (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total costs for each corresponding reimbursable costs center totals as reported on Worksheet B. The Worksheet B totals were based on the sum of reimbursable costs reported on lines 8 through 17. For example, the salary percentage for Supplies (as measured by line 9 on Worksheet A) was applied to the total expenses for the Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8 through 17). This provided us with an estimate of Non-Direct Patient Care Wages and Salaries.

Step 3: The estimated Wages and Salaries for each of the cost centers on Worksheet B derived in step 2 were subsequently summed and added to the direct patient care wages and salaries costs.

Step 4: The estimated non-direct patient care wages and salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

Using this methodology, we derive a proposed Wages and Salaries cost weight of 32.6 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.1 percent and non-direct patient care wages and salaries cost weight of 7.5 percent, as seen in Table 3.

The final adjustment made to this category is to include Contract Labor

costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses, we propose to remove the estimated cost weight for the contract labor costs from the Administrative and General category (where we believe the majority of the contract labor costs would be reported) to the Wages and Salaries category. We are proposing to use data from the SAS (2012 data inflated to 2016), which reported 2.3 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to Wages and Salaries. At the same time, we subtracted that same amount from Administrative and General, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category for the 2012-based ESRDB market basket.

The resulting proposed cost weight for Wages and Salaries increases to 34.5 percent when contract labor wages are added. The calculation of the proposed Wages and Salaries cost weight for the 2016-based ESRDB market basket is shown in Table 3 along with the similar calculation for the 2012-based ESRDB market basket.

TABLE 3—PROPOSED 2016 AND 2012 ESRD WAGES AND SALARIES COST WEIGHT DETERMINATION

| Components | Proposed 2016 cost weight (percent) | 2012 cost weight (percent) | Source |
|--|--|----------------------------------|---|
| Wages and Salaries Direct Patient Care | 25.1 7.5 1.9 | 8.6 | MCR. MCR. 80% of SAS Contract Labor weight. |
| Total Wages and Salaries | 34.5 | 33.7 | |

Employee Benefits

The Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2016) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

In order to reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, data from the SAS benefits share includes expenses related to the retirement and pension benefits. In order to be consistent with the cost report definitions we do not want to include the costs associated with retirement and pension benefits in the cost share weights. These costs are relatively small compared to the costs for the health-related benefits,

accounting for only 2.7 percent of the total benefits costs as reported on the SAS. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.6 percentage points higher (8.6 vs. 7.0) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid doublecounting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.6 percentage points for Non-Direct Patient Care Employee Benefits from the Administrative and General cost category (where we believe the majority of the contract labor costs would be reported).

The final adjustment made to this category is to include contract labor benefit costs. Once again, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A,

Column 3 and cannot be disentangled using the MCR data. Identical to our methodology above for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. The resulting cost weight for Employee Benefits increases to 9.1 percent when contract labor benefits are added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2012-based ESRDB market basket.

The Table 4 compares the 2012-based Benefits cost share derivation as detailed in the CY 2015 ESRD proposed rule (79 FR 40218) to the proposed 2016-based Benefits cost share derivation.

TABLE 4—PROPOSED 2016 AND 2012 ESRD EMPLOYEE BENEFITS COST WEIGHT DETERMINATION

| Components | Proposed 2016 cost weight (percent) | 2012 cost weight (percent) | Source |
|---|--|----------------------------------|---|
| Employee Benefits Direct Patient Care Employee Benefits Non-direct Patient Care Contract Labor (Benefits) | | 1.8 | MCR. SAS. 20% of SAS Contract Labor weight. |
| Total Employee Benefits | 9.1 | 8.8 | |

Pharmaceuticals

The proposed 2016-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceutical cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: 11 "Drugs Included in Composite Rate"; 12 "Erythropoiesis stimulating agents (ESAs)"; 13 "ESRD-Related Drugs". We also added the drug expenses reported on line 5 column 10

"Non-ESRD related drugs". The Non-ESRD related drugs would include drugs and biologicals administered during dialysis for non-ESRD related conditions as well as oral-only drugs. Since these are costs to the facility for providing ESRD treatment to the patient, we propose to continue to include them in the Pharmaceutical cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug.

Since these vaccines are not reimbursable under the ESRD PPS, we exclude them from the proposed 2016-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced above. This resulted in a proposed ESRDB market basket weight for Pharmaceuticals of 12.4 percent. ESA expenditures accounted for 10.0 percentage points of the proposed Pharmaceuticals cost weight, and All

Other Drugs accounted for the remaining 2.4 percentage points.

The Pharmaceutical cost weight decreased 4.1 percentage point from the 2012-based ESRD market basket to the proposed 2016-based ESRD market basket (16.5 percent to 12.4 percent). Most providers experienced a decrease in their Pharmaceutical cost weight since 2012. One provider in particular, a major dialysis provider, experienced a significant pharmaceutical cost weight decline in 2016. This provider's decline has an effect on the overall Pharmaceutical cost weight in the proposed 2016-based ESRDB market basket. We wish to note that the provider's decline in the pharmaceutical cost weight was found across the board in all states where the provider has facilities. Given this, we are proposing to include this provider's decline in our market basket results treating it as a 'real' change in relative pharmaceutical costs. We are not proposing to use an alternative methodology, such as averaging cost weights from multiple years, as proposed for Lab Services.

Supplies

We calculated the Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting proposed 2016-based ESRDB market basket weight for Supplies is 10.4 percent, about the same as the weight for the 2012-based ESRDB market basket.

Lab Services

We calculated the Lab Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Lab Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The proposed 2016-based ESRDB market basket weight for Lab Services is estimated at 2.2 percent.

The 2016 Lab Services expenses reported for a main chain provider were significantly lower than those reported in the 3 years prior (2013–2015) and lower than the 2016 Lab Services weight for all other providers. We believe the lower costs were based on a correction to the way that this chain is billing for these services, an assumption that is supported by the findings of a January 2016 Health and Human Services Office

of the Inspector General (OIG) Report.² Because the recent reported costs from this chain reflect these unique circumstances, we propose to take a 2year average of Lab Services costs for 2015 and 2016 for this chain in order to smooth out the year-to-year volatility. This approach results in a Lab cost weight for this chain that is higher than it was in 2012, which is then added to the 2016 Lab Services costs for all other providers, where the cost weight was similar in 2012 and 2016. As a result, the overall Lab Services cost weight increased 0.7 percentage points from the 2012-based ESRDB market basket to the proposed 2016-based ESRD market basket.

Housekeeping and Operations

We calculated the Housekeeping and Operations cost weight using the costs reported on Worksheet A, lines 3 and 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping and Operations category was reduced to exclude the estimated share of Non-Direct Patient Care Waged and Salaries associated with this cost center. These costs were divided by total costs to derive a proposed 2016-based ESRDB market basket weight for Housekeeping and Operations of 3.9 percent.

Capital

We developed a proposed market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because Housekeeping and Operations and Maintenance costs are included in the Worksheet B cost center for Capital-Related costs (Worksheet B. column 2). we excluded the costs for these two categories and developed a separate expenditure category for Housekeeping and Operations, as detailed above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care Wages and Salaries and Benefits associated with the Capital-related cost centers. We used Worksheet B to develop two capital-related cost categories: (1) Buildings and Fixtures (Worksheet B, the sum of lines 8 through 17, column

2 less housekeeping & operations as derived from expenses reported on Worksheet A (see above)), and (2) Machinery (Worksheet B, the sum of lines 8 through 17, column 4). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Equipment could move differently than those associated with Machinery, we continue to believe that two capitalrelated cost categories are appropriate. The resulting proposed 2016-based ESRDB market basket weights for Capital-related Buildings and Fixtures and Capital-related Machinery are 9.2 and 3.8 percent, respectively.

Administrative and General

We computed the proportion of total Administrative and General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we remove contract labor from this cost category and apportion these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting Administrative and General cost weight is 14.5 percent.

We are proposing to further disaggregate the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Water and Sewerage, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights are derived by inflating the detailed 2012 SAS data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 SAS data. We repeat this practice for each year to 2016. We then calculate the cost shares that each cost category represents of the 2012 data inflated to 2016. These resulting 2016 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the proposed 2016-based ESRD market basket. This method is similar to the method used for the 2012-based ESRDB market basket.

Table 5 lists all of the cost categories and cost weights in the proposed 2016-

² Review of Medicare Payments for Laboratory Tests Billed with an AY Modifier by Total Renal Laboratories, Inc.; https://oig.hhs.gov/oas/reports/ region1/11400505.pdf.

based ESRDB market basket compared to the 2012-based ESRDB market basket.

TABLE 5—COMPARISON OF THE PROPOSED 2016-BASED AND THE 2012-BASED ESRDB MARKET BASKET COST CATEGORIES AND WEIGHTS

| Proposed 2016 cost category | Proposed 2016 cost weights (percent) | 2012 cost weights (percent) |
|---------------------------------------|---|-----------------------------------|
| Total | 100.0 | 100.0 |
| Compensation | 43.6 | 42.5 |
| Wages and Salaries | 34.5 | 33.7 |
| Employee Benefits | 9.1 | 8.8 |
| Utilities | 2.0 | 1.8 |
| Electricity | 1.1 | 1.0 |
| Natural Ġas | 0.1 | 0.1 |
| Water and Sewerage | 0.8 | 0.8 |
| Medical Materials and Šupplies | 24.9 | 28.1 |
| Pharmaceuticals | 12.4 | 16.5 |
| ESAs | 10.0 | 12.9 |
| Other Drugs (except ESAs) | 2.4 | 3.6 |
| Supplies | 10.4 | 10.1 |
| Lab Services | 2.2 | 1.5 |
| All Other Goods and Services | 16.4 | 15.3 |
| Telephone & Internet Services | 0.5 | 0.5 |
| Housekeeping and Operations | 3.9 | 3.8 |
| Professional Fees | 0.7 | 0.6 |
| All Other Goods and Services | 11.3 | 10.4 |
| Capital Costs | 13.0 | 12.2 |
| Capital Related-Building and Fixtures | 9.2 | 8.4 |
| Capital Related-Machinery | 3.8 | 3.9 |

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

b. Proposed Price Proxies for the 2016-Based ESRDB Market Basket

After developing the cost weights for the proposed 2016-based ESRDB market basket, we are proposing to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based the proposed price proxies on Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

(1) Employment Cost Indexes. Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

(2) *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price

changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

(3) Consumer Price Indexes.

Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs were available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this helps to ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this provision meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 7 lists all price proxies for the proposed 2016-based ESRDB market

basket. We note that we are proposing to use the same proxies as those used in the 2012-based ESRDB market basket. Below is a detailed explanation of the price proxies used for each cost category weight.

Wages and Salaries

We are proposing to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the proposed 2016-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2016 FTE data from the MCR data and associated 2016 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2012-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related

We are proposing to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered ("Hospitals" and "Health Care and Social Assistance"), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage

distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.9 percent of total Wages and Salaries in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Health Related subcategory include "Physicians," "Registered Nurses," "Licensed Practical Nurses," "Nurses' Aides," "Technicians," and "Dieticians".

Management

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries— Management subcategory weight within the Wages and Salaries cost category is 6.7 percent in 2016. The ESRD Medicare Cost Report FTE category used to define the Wages and Salaries—Management subcategory is "Management."

Administrative

We are proposing to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries— Administrative subcategory weight within the Wages and Salaries cost category is 7.7 percent in 2016. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is "Administrative."

Services

We propose using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 5.7 percent in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Services subcategory are "Social Workers" and "Other."

Table 6 lists the four ECI series and the corresponding weights used to construct the proposed ECI blend for Wages and Salaries compared to the 2012-based weights for the subcategories. We believe this ECI blend is the most appropriate price proxy to measure the growth of wages and salaries faced by ESRD facilities.

TABLE 6—PROPOSED ECI BLEND FOR WAGES AND SALARIES IN THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

| Cost category | ECI series | Proposed 2016 weight (percent) | 2012 Weight (percent) |
|----------------|---|--------------------------------------|--------------------------|
| Health Related | ECI for Wages and Salaries for All Civilian Workers in Hospitals | 79.9 | 79.0 |
| Management | ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial. | 6.7 | 8.0 |
| Administrative | ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support. | 7.7 | 7.0 |
| Services | ECI for Wages and Salaries for Private Industry Workers in Service Occupations. | 5.7 | 6.0 |

Employee Benefits

We are proposing to continue using an ECI blend for Employee Benefits in the proposed 2016-based ESRDB market basket where the components match those of the proposed Wage and Salaries ECI blend. The proposed occupation weights for the blended Benefits price proxy are the same as those proposed for the wages and salaries price proxy blend as shown in Table 5. BLS does not

publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related

We are proposing to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU1016220000000I) and the relative importance of Wages and Salaries within Total Compensation as

published by BLS. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section.

Management

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2010000110000I) and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason

stated above in the Wages and Salaries price proxy section.

Administrative

We are proposing to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2010000220000I) and the relative importance of Wages and Salaries within Total Compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the wages and salaries price proxy section.

Services

We are proposing to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU2030000300000I) to measure price growth of this subcategory. We believe this ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section

We feel the proposed benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 7 lists the four ECI series and the corresponding weights used to construct the proposed benefits ECI blend.

TABLE 7—PROPOSED ECI BLEND FOR BENEFITS IN THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

| Cost category | ECI series | Proposed 2016 weight (percent) | 2012 Weight (percent) |
|----------------|---|--------------------------------------|--------------------------|
| Health Related | ECI for Benefits for All Civilian Workers in Hospitals | 79.9 | 79.0 |
| Management | ECI for Benefits for Private Industry Workers in Management, Business, and Financial. | 6.7 | 8.0 |
| Administrative | ECI for Benefits for Private Industry Workers in Office and Administrative Support. | 7.7 | 7.0 |
| Services | ECI for Benefits for Private Industry Workers in Service Occupations | 5.7 | 6.0 |

Electricity

We propose to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

We propose to continue using the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category.

Water and Sewerage

We propose to continue using the CPI U.S. city average for Water and Sewerage Maintenance (BLS series code #CUUR0000SEHG01) to measure the price growth of this cost category.

Pharmaceuticals

We propose to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. We propose to continue using the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807) for all other drugs included in the bundle other than ESAs.

The PPI-BPHU measures the price change of prescription biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in this price index. However, we believe the PPI-BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI-BPHU. We did this by comparing the historical price changes in the PPI-BPHU and the ASP for ESAs and found the cumulative growth to be consistent over the past 4 years. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI-BPHU is still an appropriate price proxy.

Additionally, since the non-ESA drugs used in the treatment of ESRD are mainly vitamins and nutrients, we believe that the PPI–VNHP continues to be the best available proxy for these types of drugs. While this index does include over-the-counter drugs as well

as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows similar growth to the proposed PPI–VNHP.

Supplies

We propose to continue using the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category.

Lab Services

We propose to continue using the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category.

Telephone Service

We propose to continue using the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category.

Housekeeping and Operations

We propose to continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category.

Professional Fees

We propose to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code # CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

We propose to continue using the PPI Commodity for Final demand—Finished Goods Less Foods and Energy (BLS series code #WPUFD4131) to measure the price growth of this cost category.

Capital-Related Building and Equipment

We propose to continue using the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of this cost category.

Capital-Related Machinery

We propose to continue using the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category.

Table 8 shows all the proposed price proxies and cost weights for the proposed 2016-based ESRDB Market Basket.

TABLE 8—PROPOSED PRICE PROXIES AND ASSOCIATED COST WEIGHTS FOR THE 2016-BASED ESRDB MARKET BASKET

| Cost category | Price proxy | Proposed 2016 cost weight |
|---|---|---------------------------------|
| Total ESRDB market basket | | 100.0 |
| Compensation | | 43.6 |
| Wages and Salaries | | 34.5 |
| Health-related | ECI for Wages and Salaries for All Civilian Workers in Hospitals | 27.6 |
| Management | ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial. | 2.3 |
| Administrative | ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support. | 2.7 |
| Services | ECI for Wages and Salaries for Private Industry Workers in Service Occupations | 2.0 |
| Employee Benefits | , | 9.1 |
| Health-related | ECI for Total Benefits for All Civilian workers in Hospitals | 7.3 |
| Management | ECI for Total Benefits for Private Industry workers in Management, Business, and Financial. | 0.6 |
| Administrative | ECI for Total Benefits for Private Industry workers in Office and Administrative Sup- | 0.7 |
| | port. | *** |
| Services | ECI for Total Benefits for Private Industry workers in Service Occupations | 0.5 2.0 |
| Utilities | DDI Commondity for Commondate Floring Power | |
| Electricity | PPI Commodity for Commercial Electric Power | 1.1 |
| Natural Gas | PPI Commodity for Commercial Natural Gas | 0.1 |
| Water and Sewerage | CPI-U for Water and Sewerage Maintenance | 0.8 |
| Medical Materials and Supplies | | 24.9 |
| Pharmaceuticals | | 12.4 |
| ESAs | PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use | 10.0 |
| Other Drugs | PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations | 2.4 |
| Supplies | PPI Commodity for Surgical and Medical Instruments | 10.4 |
| Lab Services | PPI Industry for Medical Laboratories | 2.2 |
| All Other Goods and Services | | 16.4 |
| Telephone Service | CPI–U for Telephone Services | 0.5 |
| Housekeeping and Operations | PPI Commodity for Cleaning and Building Maintenance Services | 3.9 |
| Professional Fees | ECI for Total Compensation for Private Industry Workers in Professional and Related. | 0.7 |
| All Other Goods and Services | PPI for Final demand—Finished Goods less Foods and Energy | 11.3 |
| Capital Costs | | 13.0 |
| Capital Related Building and Equipment. | PPI Industry for Lessors of Nonresidential Buildings | 9.2 |
| Capital Related Machinery | PPI Commodity for Electrical Machinery and Equipment | 3.8 |

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

ii. Proposed CY 2019 ESRD Market Basket Update, Adjusted for Multifactor Productivity

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. We propose to use the 2016-based ESRDB market basket as described in this proposed rule to compute the CY 2019 ESRDB market basket increase factor and labor-related share. Consistent with

historical practice, we estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

a. Market Basket Update

Using this methodology and the IGI forecast for the first quarter of 2018 of the proposed 2016-based ESRDB market basket (with historical data through the

fourth quarter of 2017), and consistent with our historical practice of estimating market basket increases based on the best available data, the proposed CY 2019 ESRDB market basket increase factor is 2.2 percent.

b. Multifactor Productivity (MFP)

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235). The most up-to-date MFP projection methodology is available on the CMS website at http:// www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/ MarketBasketResearch.html. We are not proposing any changes to the

methodology for the projection of the MFP adjustment.

Using IGI's first quarter 2018 forecast, the proposed MFP adjustment for CY 2019 (the 10-year moving average of MFP for the period ending CY 2019) is projected to be 0.7 percent.

c. Market Basket Update Adjusted for Multifactor Productivity (MFP)

As a result of these provisions, the proposed CY 2019 ESRD market basket increase is 1.5 percent. This market basket increase is calculated by starting with the proposed 2016-based ESRDB market basket percentage increase factor of 2.2 percent for CY 2019, and reducing it by the MFP adjustment (the 10-year moving average of MFP for the period

ending CY 2019) of 0.7 percentage point. We are also proposing that if more recent data are subsequently available (for example, a more recent estimate of the market basket increase or MFP adjustment), we would use such data to determine the market basket increase and MFP adjustment in the CY 2019 ESRD PPS final rule.

The CY 2019 ESRDB increase factor would be the same if we used the 2012-based ESRDB market basket. That is, the CY 2019 ESRDB market basket increase factor is 2.2 percent using the 2012-based ESRDB market basket. Table 9 shows the increase factors under the proposed 2016-based ESRDB and 2012-based ESRDB market basket.

TABLE 9—HISTORICAL AND PROJECTED INCREASE FACTORS UNDER THE PROPOSED 2016-BASED AND 2012-BASED ESRDB MARKET BASKET

| Calendar year (CY) | Proposed 2016-Based ESRDB market basket | 2012-Based ESRDB market basket |
|-----------------------|--|--------------------------------------|
| Historical Data: | | |
| CY 2015 | 2.0 | 2.2 |
| CY 2016 | 1.9 | 2.0 |
| CY 2017 | 1.4 | 1.3 |
| Forecast: | | |
| CY 2018 | 1.9 | 1.9 |
| CY 2019 | 2.2 | 2.2 |

Source: IHS Global Inc. 1st quarter 2018 forecast with historical data through 4th quarter 2017.

iii. Proposed Labor-Related Share for ESRD PPS

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits,

Professional Fees, Labor-related Services, and a portion of Capital from a given market basket.

We propose to use the proposed 2016-based ESRDB market basket cost weights to determine the proposed labor-related share for ESRD facilities. Therefore, effective for CY 2019, we are proposing a labor-related share of 52.3 percent, slightly higher than the current 50.673 percent that was based on the 2012-based ESRD market basket, as shown in Table 10 below. We propose to move the labor-related share to a one

decimal level of precision rather than the three decimal level of precision used previously. CMS is migrating all payment system labor-related shares to a one decimal level of precision. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below). We used the same methodology for the 2012-based ESRD market basket.

TABLE 10—PROPOSED CY 2019 LABOR-RELATED SHARE AND CY 2018 LABOR-RELATED SHARE

| Cost category | Proposed CY 2019 ESRD labor-related share | CY 2018 ESRD labor-related share |
|-----------------------------------|--|---|
| Wages and salaries | 34.5 | 33.650 |
| Employee Benefits | 9.1 | 8.847 |
| Housekeeping and Operations | 3.9 | 3.785 |
| Professional Fees (Labor-Related) | 0.6 | 0.537 |
| Capital Labor-Related | 4.2 | 3.854 |
| Total Labor-Related Share | 52.3 | 50.673 |

The labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local

labor market (87 percent). We conducted a survey of ESRD facilities in

2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we are proposing to include 87 percent of the cost weight for Professional Fees in the labor-related share (87 percent is the same percentage as used in prior years).

The labor-related share for capitalrelated expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related Building and Equipment expenses). Capitalrelated expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

b. The Proposed CY 2019 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area

designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at https://www.whitehouse.gov/omb/bulletins/.

For CY 2019, we would update the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize prefloor hospital data that are unadjusted for occupational mix. The proposed CY 2019 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the proposed CY 2019 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS Web site at https://www.cms.gov/ Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, see CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we

finalized a decision to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.5500 and 0.5000, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), however, we decided to maintain a wage index floor of 0.4000, rather than further reduce the floor by 0.05. We needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders could provide useful input for consideration in future decision-making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, we finalized a wage index floor of 0.4000 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 final rule (82 FR 50747), we finalized a policy to permanently maintain the wage index floor of 0.4000, because we believed it was appropriate and provided additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

ii. Wage Index Floor for CY 2019 and Subsequent Years

For CY 2019 and subsequent years, we are proposing to increase the wage

index floor to 0.5. This wage floor increase is responsive to stakeholder comments, safeguards access to care in areas at the lowest end of the current wage index distribution, and is supported by data, as discussed below, which supports a higher wage index floor. Stakeholders, particularly those located in Puerto Rico, have expressed the adverse impact the low wage index floor value has on a facility, such as closure and the resulting impact on access to care. Also, natural disasters (for example, hurricanes, floods) common to this geographic area can cause significant infrastructure issues, create limited resources, and create conditions that may accelerate kidney failure in patients predisposed to chronic kidney disease, all of which have a significant impact on renal dialysis services. These negative effects of natural disasters on the local economy impact wages and salaries. For example, there is the potential of the outmigration of qualified staff that would cause a facility the need to change their hiring practices or increase the wages that they would otherwise pay had their not been a natural disaster.

In response to the CY 2018 ESRD proposed rule, commenters described the economic and healthcare crisis in Puerto Rico and recommended that CMS use the U.S. Virgin Islands wage index for payment rate calculations in Puerto Rico as a proxy for CY 2018.

Commenters indicated that the primary issue is that Puerto Rico hospitals report comparatively lower wages that are not adjusted for occupational mix and, as indicated in the CY 2017 ESRD PPS proposed rule (81 FR 42817), in Puerto Rico, only registered nurses (RNs) can provide dialysis therapy in the outpatient setting. This staffing variable artificially lowers the reportable index values even though the actual costs of dialysis service wages in Puerto Rico are much higher than the data CMS is relying upon. In addition, several commenters stated that non-labor costs, including utilities and shipping costs and the CY 2015 change in the labor-share based on the rebased and revised ESRDB market basket compound the issue even further.

One organization stated that it does not believe maintaining the current wage index for Puerto Rico for CY 2018 is enough to offset the poor economic conditions, high operational costs and epidemiologic burden of ESRD on the island.

Since we did not propose to change the wage index floor or otherwise change the wage indexes for Puerto Rico, we maintained the wage index floor of 0.4000 for CY 2018. We noted that the current wage index floor and labor-related share have been in effect since CY 2015 and neither the floor nor the labor share has been reduced since then. More importantly, the wage index is solely intended to reflect differences in labor costs and not to account for non-labor cost differences, such as utilities or shipping costs (82 FR 50747).

With regard to staffing in Puerto Rico facilities, we noted that ESRD facilities there utilize RNs similarly to ESRD facilities on the mainland, that is, facilities utilize dialysis technicians and aides to provide dialysis services with oversight by an RN and that hourly wages for RNs and dialysis support staff were approximately half of those salaries in mainland ESRD facilities. For those reasons, we do not agree that the hospital-reported data is unreliable, and we believe using that data is more appropriate than applying the wage index value for the Virgin Islands where salaries are considerably higher.

Even though we did not propose a change in the wage index floor for CY 2018, we continued to analyze the cost of furnishing dialysis care in Puerto Rico, staffing in Puerto Rico ESRD facilities and hospital wage data. While we found the analyses to be inconclusive for the CY2018 ESRD PPS final rule (82 FR 50746), in light of the recent natural disasters that profoundly impacted delivery of ESRD care in Puerto Rico, we revisited the analyses and concluded that we should propose a new wage index floor. We conducted various analyses to test the reasonableness of the current wage index floor value of 0.4000. The details of these analyses and our proposal are provided below.

a. Analysis of Puerto Rico Cost Reports

We performed an analysis using cost reports and wage information specific to Puerto Rico from the BLS (https://www.bls.gov/oes/2015/may/oes_pr.htm). The analysis used data from cost reports for freestanding facilities and hospital-based facilities in Puerto Rico for CYs 2013 through 2015 are as follows:

- The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities. Note that the available variables differ between these two sources. For freestanding facilities, data were obtained regarding treatment counts, costs, salaries, benefits, and FTEs by labor category. For hospital-based facilities, a more limited set of variables are available for treatment counts and FTEs.
- We annualized cost report data for each facility in order to create one cost

report record per facility per calendar. If cost report forms were submitted at a non-calendar-year cycle, multiple cost report records were proportionated and combined in order to create an annualized cost report record.

• We calculated weighted means across all facilities for each variable. The means were weighted by treatment counts, where facilities with more treatment counts contributed more to the value of the overall mean.

Using this data, we calculated alternative wage indices for Puerto Rico that combined labor quantities (FTEs) from cost reports with BLS wage information to create two regular Laspeyres price indexes. The Laspeyres index can be thought of as a price index in which there are two prices for goods (prices for labor FTEs in Puerto Rico and the mainland U.S.), where the distribution of goods (labor share of FTEs) is held constant (across Puerto Rico and the U.S.). The first index used quantity weights from the overall U.S. use of labor inputs. The second index used quantity weights from the PR use of labor inputs.

The alternative wage indices derived from the analysis indicate that Puerto Rico's wage index likely lies between 0.5100 and 0.5500. Both of these values are above the current wage index floor and suggest that the current 0.4000 wage index floor may be too low.

b. Statistical Analysis of the Distribution of the Wage Index

We also performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution.

In the general sense, an outlier is an observation that lies an abnormal distance from other values in a population. In this case, the population of values is the various wage indices within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 - Q1)is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5.

First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the

IQR: IQR = 0.9881 - 0.8303 = 0.578. Finally, we identified the inner fence values as shown below.

Lower inner fence: Q1 – 1.5 * IQR = $0.8303 - (1.5 \times 0.1578) = 0.5936$ Upper inner fence: Q3 + 1.5 * IQR = $.881 + (1.5 \times 0.1578) = 1.2248$

This statistical outlier analysis demonstrates that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also may suggest that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we are proposing a wage index floor of 0.5000. We believe this increase from the current 0.4000 wage index floor value minimizes the impact to the base rate while providing increased payment to areas that need it. We considered the various wage index floor values based on our analyses. While the statistical analysis supports our decision to propose a higher wage index floor, the cost report analysis is more definitive as it is based on reported wages using an alternative data source. As a result, we considered wage index floor values between 0.4000 and 0.5500 and are proposing 0.5000 in an effort to strike a balance between providing additional payments to affected areas while minimizing the impact on the base rate. We believe the proposed 25 percent increase from the current 0.4000 value would help to address stakeholder requests for a higher wage index floor, minimize patient access issues, and would have a lower impact to the base rate than if we proposed a higher wage index floor value.

The wage index floor directly affects the base rate and currently, only rural Puerto Rico and four urban CBSAs in Puerto Rico receive the wage index floor of 0.4000. The next lowest wage index is in the Wheeling, West Virginia CBSA with a value of 0.6599. Under this proposal, all CBSAs in Puerto Rico would receive the wage index floor of 0.5000. Though the proposed wage index value currently affects CBSAs in Puerto Rico, we note that, consistent with our established policy, any CBSA that falls below the floor would be eligible to receive the floor. We solicit comment on the proposal to increase the wage index floor from 0.4000 to 0.5000 for CY 2019 and beyond.

iii. Application of the Wage Index Under the ESRD PPS

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In section II.B.3.b of this proposed rule, we are proposing the labor-related share of 52.3 percent, which is based on the proposed 2016-based ESRDB market basket. Thus, for CY 2019, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

iv. New Urban Core-Based Statistical Area (CBSA)

On August 15, 2017, OMB issued OMB Bulletin No. 17-01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17-01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17-01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

• Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB Web site at https:// www.whitehouse.gov/sites/ whitehouse.gov/files/omb/bulletins/ 2017/b-17-01.pdf. We did not have sufficient time to include this change in the computation of the proposed CY 2019 wage index, rate setting, and Addenda associated with this proposed rule. This new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of the hospital located in this new CBSA. In this proposed rule, we are providing an estimate of this new area's wage index based on the average hourly wage, unadjusted for occupational mix, for new CBSA 46300 and the national average hourly wages from the wage data for the proposed CY 2019 wage index. Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the proposed wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002).

Taking the estimated unadjusted average hourly wage of \$35.833564813 of the new CBSA 46300 and dividing by the national average hourly wage of \$42.990625267 results in the proposed estimated wage index of 0.8335 for CBSA 46300.

In the final rule, we would incorporate this change into the final CY 2019 ESRD PPS wage index, rate setting and Addenda associated with the final rule. Thus, for CY 2019, we would use the OMB delineations that were adopted beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01.

c. Proposed CY 2019 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) ESRDrelated drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRDrelated oral-only drugs effective January 1, 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by

Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described below) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP

amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For CY 2019, we propose that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2017. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any

future outlier payments, we propose the outlier thresholds for CY 2019 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2017. We recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

In the CY 2018 ESRD PPS final rule (82 FR 50748), we stated that based on the CY 2016 claims data, outlier payments represented approximately 0.78 percent of total payments. For this proposed rule, as discussed below, CY 2017 claims data show outlier payments represented approximately 0.80 percent of total payments.

i. CY 2019 Update to the Outlier Services Medicare Allowable Payment (MAP) Amounts and Fixed Dollar Loss (FDL) Amounts

For CY 2019, we propose to update the outlier services MAP amounts and FDL amounts to reflect the utilization of outlier services reported on 2017 claims. For this proposed rule, the outlier services MAP amounts and FDL amounts were updated using 2017 claims data. The impact of this update is shown in Table 11, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2017 with the updated proposed estimates for this rule. The estimates for the proposed CY 2019 outlier policy, which are included in Column II of Table 11, were inflation adjusted to reflect projected 2019 prices for outlier services.

TABLE 11—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

| | Final outlier pol (based on 20 | (based on 2016 data, price | | nn II utlier policy 2019 7 data, price o 2019) |
|--|-----------------------------------|----------------------------|---------|--|
| | Age <18 | Age >=18 | Age <18 | Age >=18 |
| Average outlier services MAP amount per treatment | 37.41 | 44.27 | 34.33 | 41.97 |
| Standardization for outlier services | 1.0177 | 0.9774 | 1.0588 | 0.9786 |
| MIPPA reduction | 0.98 | 0.98 | 0.98 | 0.98 |
| Adjusted average outlier services MAP amount | \$37.31 | \$42.41 | \$35.62 | \$40.25 |
| Fixed-dollar loss amount that is added to the predicted MAP to determine | | | | |
| the outlier threshold | \$47.79 | \$77.54 | \$47.88 | \$69.73 |
| Patient-months qualifying for outlier payment | 9.0% | 7.4% | 9.2% | 8.0% |

^{*}Note that Column I was obtained from Column II of Table 1 from the CY 2018 ESRD PPS final rule (82 FR 50749).

As demonstrated in Table 11, the estimated FDL amount per treatment that determines the CY 2019 outlier threshold amount for adults (Column II; \$69.73) is lower than that used for the

CY 2018 outlier policy (Column I; \$77.54). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from \$42.41 to \$40.25. For

pediatric patients, there is a slight increase in the FDL amount from \$47.79 to \$47.88. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from \$37.31 to \$35.62.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2019 will be 8.0 percent for adult patients and 9.2 percent for pediatric patients, based on the 2017 claims data. The pediatric outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. Based on the 2017 claims, outlier payments represented approximately 0.80 percent of total payments, slightly below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2017 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2019. We believe the update to the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL which is more in line with current outlier services utilization rates. We note that recalibration of the FDL amounts in this proposed rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

iii. Solicitation on the Expansion of the Outlier Policy

Currently, former separately payable Part B drugs, laboratory services, and supplies are eligible for the outlier payment. In the interest of promoting innovation, ensuring appropriate payment for all drugs and biologicals, and as a complement to the TDAPA proposals, we are soliciting comment on whether we should expand the outlier policy to include composite rate drugs and supplies. With the proposed expansion to the drug designation

process discussed in section II.B.1.f of this proposed rule, such expansion of the outlier policy could promote appropriate payment for composite rate drugs once the TDAPA period has ended. Additionally, with regard to composite rate supplies, an expansion of the outlier policy could promote use of new innovative devices or items that would otherwise be considered in the bundled payment. If commenters believe such an approach is appropriate, we are requesting they provide input on how we would effectuate such a shift in policy. For example, the reporting of these services may be challenging since they have never been reported on ESRD claims previously. We are particularly interested in feedback about how such items might work under the existing outlier framework or whether specific changes to the policy to accommodate such items are needed. We will consider all comments and address by making proposals, if appropriate, in future rulemaking.

d. Proposed Impacts to the CY 2019 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the pertreatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment and training adjustment add-on.

ii. Annual Payment Rate Update for CY 2019

We are proposing an ESRD PPS base rate for CY 2019 of \$235.82. This update reflects several factors, described in more detail as follows:

- Market Basket Increase: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2019 projection for the proposed ESRDB market basket is 2.2 percent. In CY 2019, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed above, the proposed MFP adjustment for CY 2019 is 0.7 percent, thus yielding a proposed update to the base rate of 1.5 percent for CY 2019. Therefore, the proposed ESRD PPS base rate for CY 2019 before application of the wage index budgetneutrality adjustment factor would be $$235.86 ($232.37 \times 1.0150 = $235.86).$
- Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2019, we are not proposing any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the proposed CY 2019 wage index budget-neutrality adjustment factor using treatment counts from the 2017 claims and facility-specific CY 2018 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2018. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2019. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the ESRD wage index for CY 2019. The total of these payments becomes the new CY 2019 amount of wage-adjusted expenditures for all ESRD facilities. The wage index budgetneutrality factor is calculated as the target amount divided by the new CY 2019 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2019 estimated payments, aggregate payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that wage index adjustments do not increase or decrease aggregate

Medicare payments with respect to changes in wage index updates.

The CY 2019 proposed wage index budget-neutrality adjustment factor is 0.999833. This application would yield a CY 2019 ESRD PPS proposed base rate of \$235.82 ($$235.75 \times 0.999833 = 235.82).

In summary, we are proposing a CY 2019 ESRD PPS base rate of \$235.82. This amount reflects a proposed market basket increase of 1.5 percent and the proposed CY 2019 wage index budgetneutrality adjustment factor of 0.999833.

C. Solicitation for Information on Transplant and Modality Requirements

When an individual is faced with failing kidneys, life-extending treatment is available. The most common treatment is dialysis, but the best treatment is receiving a kidney transplant from a living or deceased donor. Dialysis, either HD or PD, can sustain life by removing impurities and extra fluids but cannot do either job as consistently or efficiently as a functioning kidney. Dialysis also carries risks of its own, including anemia, bone disease, hypotension, hypertension, heart disease, muscle cramps, itching, fluid overload, nerve damage, depression, and infection. Timely transplantation, despite requiring a major surgery and ongoing medication, offers recipients a longer, higher quality of life, without the ongoing risks of dialysis. Unfortunately, the number of people waiting for healthy donor kidneys far exceeds the number of available organs. In 2015, the most recent year for which complete data is available, 18,805 kidney transplants were performed in the U.S., while over 80,000 individuals remained on waiting lists (https://www.usrds.org/2017/view/ v2 06.aspx). That same year, there were 124,114 newly reported cases of ESRD and over 703,243 prevalent cases of ESRD (https://www.usrds.org/2017/ view/v2 01.aspx).

In recognition of the superiority of transplantation but the need for dialysis, CMS has required for nearly 10 years that Medicare-certified dialysis facilities evaluate all patients for transplant suitability and make appropriate referrals to local transplant centers (73 FR 20370). Specifically, dialysis facilities must:

facilities must:

• Inform every patient about all treatment modalities, including transplantation (§ 494.70(a)(7)).

- Évaluate every patient for suitability for a transplantation referral (§ 494.80(b)(10)).
- Document any basis for non-referral in the patient's medical record (§ 494.80(b)(10)).

- Develop plans for pursuing transplantation for every patient who is a transplant referral candidate (§ 494.90(a)(7)(ii)).
- Track the results of each kidney transplant center referral (§ 494.90(c)(1)).
- Monitor the status of any facility patients who are on the transplant waitlist (§ 494.90(c)(2)).
- Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status (§ 494.90(c)(3)).
- Educate patients, family members, or caregivers or both about transplantation, as established in a patient's plan of care (§ 494.90(d)).

Despite these requirements, the percentage of prevalent dialysis patients wait-listed for a kidney has recently declined (https://www.usrds.org/2017/ view/v2 06.aspx, Figure 6.2), meaning that fewer people have the opportunity to be matched with a donor kidney. Some individuals do receive kidneys directly from suitable friends or family members, but still must be placed on the waiting list. Organ Procurement and Transplantation Network (OPTN) policy requires that all transplant recipients, including recipients of organs from living donors, be registered and added to the OPTN waiting list. Until a dialysis patient is referred to a transplant center, he or she is not able to be placed on the waiting list, and is ineligible to receive a kidney. While dialysis facilities have no control over the total supply of kidneys made available for transplantation, transplantation education, referral, and waitlist tracking are appropriate and necessary services for them to furnish. Unfortunately, there are performance gaps and disparities between dialysis facilities in providing these services.3 Therefore, as discussed in section IV.C.1.a. of section IV "End-Stage Renal Disease Quality Incentive Program (ESRD QIP)" of this proposed rule, we are proposing a reporting measure under the ESRD QIP that would track the percentage of patients at each dialysis facility who are on the kidney or kidney-pancreas transplant waiting list. We are also soliciting input on other

- ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist:
- Are there ways to ensure facilities are meeting the Conditions for Coverage (CfC) requirements, in addition to the survey process?
- Are the current dialysis facility CfC requirements addressing transplantation support services adequately, or should additional requirements be considered?

We welcome your input.

With regard to other treatment for failed kidneys, HD performed in an outpatient dialysis center is most common, followed by HD performed at home, and PD (almost always performed at home). Just as we are concerned about disparities in access to transplantation, we are also concerned about disparities in access to dialysis modality options. Although ESRD disproportionately affects racial and ethnic minority patients, minority individuals are far less likely to be treated with home dialysis than white patients.4 Home dialysis modalities necessitate a higher level of self-care than in-center care, and are not appropriate for or desired by every dialysis patient. We are concerned, however that not all dialysis patients are aware of, or given the opportunity to learn about, home modalities or their benefits—primarily greater independence and flexibility. Individuals performing home dialysis treatments are able to schedule their treatments at times most convenient for them, allowing them to coordinate with family and work schedules, and eliminate the need for thrice weekly transportation to and from a dialysis facility. The transportation savings are especially valuable to rural individuals, who might have to travel hours each week for regular treatments in a facility.

We take this opportunity to remind dialysis facilities of their responsibilities regarding modality education and options. Some dialysis facilities do not support home modalities, but all facilities are required to make appropriate referrals if a patient elects to pursue home treatments. Specifically, dialysis facilities must:

 Inform every patient about all treatment modalities, including transplantation, home dialysis modalities (home HD, intermittent PD, continuous ambulatory PD, continuous

³ R.E. Patzer, L. Plantinga, J. Krisher, S.O. Pastan, "Dialysis facility and network factors associated with low kidney transplantation rates among U.S. dialysis facilities," American Journal of Transplantation, 2014 Jul; 14(7):1562–72; and Sudeshna Paul, Laura C. Plantinga, Stephen O. Pastan, Jennifer C. Gander, Sumit Mohan, and Rachel E. Patzer, "Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities," Clinical Journal of the American Society of Nephrology, January 2018

⁴ Mehrotra, R., Soohoo, M., Rivara, M.B., Himmelfarb, J., Cheung, A.K., Arah, O.A., Nissenson, A.R., Ravel, V., Streja, E., Kuttykrishnan, S., Katz, R., Molnar, M., Kalantar-Zadeh, K., "Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States," Journal of the American Society of Nephrology December 10, 2015.

cycling PD), and in-facility HD (§ 494.70(a)(7)).

- Ensure all patients are provided access to resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients (§ 494.70(a)(7)).
- Assess every patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes (§ 494.80(a)(9)).
- Identify a plan for every patient's home dialysis or explain why the patient is not a candidate for home dialysis (§ 494.90(a)(7)(i)).
- Provide education and training, as applicable, to patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types (§ 494.90(d)).

Persons with failed kidneys often begin dialysis with no prior exposure to nephrology care or knowledge of treatment options. The practitioners and professionals who care for them are best suited to provide the necessary information to support informed, shared decision-making. Patient education is not a one-time incident, but an ongoing aspect of all health care services and settings. We welcome your suggestions on ways to ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities.

III. CY 2019 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA), Public Law 114-27, was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide

payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Annual Payment Rate Update for CY 2019

1. CY 2019 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for nonrenal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.3.d of this proposed rule, the CY 2019 proposed ESRD PPS base rate is \$235.82, which reflects the proposed ESRD bundled market basket and multifactor productivity adjustment. Accordingly, we are proposing a CY 2019 per treatment payment rate of \$235.82 for renal dialysis services furnished by ESRD facilities to individuals with AKI. This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.3.f of this proposed rule. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. As stated above, we are proposing a CY 2019 AKI dialysis payment rate of \$235.82, adjusted by the ESRD facility's wage index.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the calendar year (CY) 2018 ESRD Prospective Payment System (PPS) final rule (82 FR 50756 through 50757).

1. Improving Patient Outcomes and Reducing Burden Through the Meaningful Measures Initiative

Regulatory reform and reducing regulatory burden are high priorities for the Centers for Medicare & Medicaid Services (CMS). To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.⁵ This initiative is one component of our agency-wide Patients Over Paperwork Initiative,⁶ which is aimed at evaluating and streamlining

⁵ Meaningful Measures webpage: https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/ MMF/General-info-Sub-Page.html.

⁶Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017. Available at: https:// www.cms.gov/Newsroom/MediaReleaseDatabase/ Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.

regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that will foster operational efficiencies and will reduce costs, including collection and reporting

burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Initiative has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
 - Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based

measures where possible, such as electronic clinical quality measures);

- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 12.

TABLE 12—QUALITY PRIORITY ASSOCIATED WITH MEANINGFUL MEASURE AREAS

| Quality priority | Meaningful measure area |
|---|---|
| Making Care Safer by Reducing Harm Caused in the Delivery of Care | Healthcare-Associated Infections. |
| | Preventable Healthcare Harm. |
| Strengthen Person and Family Engagement as Partners in Their Care | Care is Personalized and Aligned with Patient's Goals. |
| | End of Life Care According to Preferences. |
| | Patient's Experience of Care. |
| | Patient Reported Functional Outcomes. |
| Promote Effective Communication and Coordination of Care | Medication Management. |
| | Admissions and Readmissions to Hospitals. |
| | Transfer of Health Information and Interoperability. |
| Promote Effective Prevention and Treatment of Chronic Disease | Preventive Care. |
| | Management of Chronic Conditions. |
| | Prevention, Treatment, and Management of Mental Health. |
| | Prevention and Treatment of Opioid and Substance Use Disorders. |
| | Risk Adjusted Mortality. |
| Work with Communities to Promote Best Practices of Healthy Living | Equity of Care. |
| , , | Community Engagement. |
| Make Care Affordable | Appropriate Use of Healthcare. |
| | Patient-focused Episode of Care. |
| | Risk Adjusted Total Cost of Care. |

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
 - Safeguarding public health;
 - Achieving cost savings;
- Improving access for rural communities; and
- · Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers as well as promoting operational efficiencies.

2. Accounting for Social Risk Factors in the ESRD OIP

In the fiscal year (FY) 2018 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule (82 FR 38237 through 38239), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also

discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by the Department of Health and Human Services, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.7 Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for

Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in CMS value-based purchasing (VBP) programs.8 As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), ASPE's report to Congress found that, in the context of VBP programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), the National Quality Forum (NQF) undertook a 2year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these

⁷ See, for example, United States Department of Health and Human Services. "Healthy People 2020: Disparities. 2014." Available at: http://www.healthypeople.gov/2020/about/foundationhealth-measures/Disparities; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

⁸ Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), "Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs." December 2016. Available at: https://aspe.hhs.gov/pdf-report/reportcongress-social-risk-factors-and-performanceunder-medicares-value-based-purchasingprograms.

measures.9 The trial period ended in April 2017 and a final report is available at: http://www.qualityforum.org/SES Trial Period.aspx. The trial concluded that "measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship" between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,10 allowing further examination of social risk factors in outcome measures.

In the FY 2018 IPPS/LTCH PPS and CY 2018 ESRD PPS proposed rules for our quality reporting and VBP programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions

about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to VBP programs, commenters also cautioned to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that VBP program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is considering options to improve health disparities among patient groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting (IQR) Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

3. Proposal To Update Regulation Text for the ESRD QIP

We are proposing to codify a number of previously adopted requirements for the ESRD QIP in our regulations by revising § 413.177 and adopting a new § 413.178. Codification of these requirements would make it easier for the public to locate these requirements.

Proposed § 413.178 would codify the following:

- Definitions of key terms used in the ESRD QIP;
- Rules for determining the applicability of the ESRD QIP to facilities, including new facilities;
 - Measure selection;
- Rules governing performance scoring, including how we calculate the total performance score;
- Our process for making ESRD QIP performance information available to the public; and
- The limitation on administrative and judicial review.

Revised § 413.177(a) would codify that an ESRD facility that does not earn enough points under the ESRD QIP to meet or exceed the minimum total performance score established for a payment year would receive up to a 2 percent reduction to its otherwise applicable payment amount under the ESRD PPS for renal dialysis services furnished during that payment year.

We welcome public comments on the proposed regulation text.

B. Proposed Update to Requirements Beginning With the PY 2021 ESRD QIP

1. Proposal To Update the PY 2021 Measure Set

In this proposed rule, we are proposing to refine and update the criteria for removing measures from the ESRD QIP measure set, and for consistency with the terminology we are adopting for other CMS quality reporting and value-based purchasing programs, we now refer to these criteria as factors. We are also proposing to remove four of the reporting measures that we previously finalized for the PY 2021 ESRD QIP measure set. Table 13 summarizes the proposed revisions to the PY 2021 ESRD QIP measure set, and we discuss the measure removal proposals in section IV.B.1.c of this proposed rule.

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET

| NQF # | Measure title and description | Measure continuing in PY 2021 |
|-------|--|-------------------------------|
| 0258 | In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure. | Yes. |
| 2496 | Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools. Standardized Readmission Ratio (SRR), a clinical measure | Yes. |

⁹ Available at: http://www.qualityforum.org/SES_ Trial Period.aspx.

¹⁰ Available at: http://www.qualityforum.org/ WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET—Continued

| NQF # | Measure title and description | Measure continuing in PY 2021 |
|--------------------|--|-------------------------------|
| 2979 | Standardized Transfusion Ratio (STrR), a clinical measure | Yes. |
| N/A | A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume (Kt/V) Dialysis Adequacy Comprehensive, a clinical measure. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the speci- | Yes. |
| 2977 | fied threshold during the reporting period. Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure. Measures the use of an AV fistula as the sole means of vascular ac- | Yes. |
| 2978 | cess as of the last hemodialysis treatment session of the month. Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure. Measures the use of a catheter continuously for 3 months or longer | Yes. |
| 1454 | as of the last hemodialysis treatment session of the month. Hypercalcemia, a clinical measure | Yes. |
| 1463 * | Standardized Hospitalization Ratio (SHR), a clinical measure | Yes. |
| 0255 | Serum Phosphorus, a reporting measure. Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum of plasma phosphorus measured at least once within month. | Proposed for Removal. |
| N/A | Anemia Management Reporting, a reporting measure. Number of months for which facility reports erythropoiesis-stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient, at least once per month. | Proposed for Removal. |
| Based on NQF #0420 | Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period. | Proposed for Removal. |
| Based on NQF #0418 | Clinical Depression Screening and Follow-Up, a reporting measure Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period. | Yes. |
| Based on NQF #0431 | National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to the Centers for Disease Control and Prevention's (CDC's) NHSN system, according to the specifications of the Healthcare, Personnel Safety Component Protocol by May 15 of the performance period. | Proposed for Removal. |
| N/A | Ultrafiltration Rate, a reporting measure | Yes. |
| Based on NQF #1460 | NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure. The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers. | Yes. |
| N/A | NHSN Dialysis Event reporting measure | Yes. |

a. Proposal To Refine and Update the Factors Used for ESRD QIP Measure Removal

Under our current policy, we consider an ESRD QIP measure for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a

measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY

2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure set would address the unique needs of a specific subset of the ESRD population (79 FR 66174). In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking, unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure and publish the justification for the removal in the Federal Register during the next rulemaking cycle. In addition, we stated that we would immediately notify ESRD facilities and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings.

In order to align with terminology we are adopting for use across a number of quality reporting and pay for performance programs, we will now refer to these criteria as "factors" rather than "criteria." We are also proposing to update these measure removal factors so that they are more closely aligned with the factors we have adopted or proposed to adopt for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of our Meaningful Measures Initiative. Specifically, we are proposing to combine current Factors 4 and 5 (proposed new Factor 4), and we are proposing to adjust the numbering of subsequent factors to account for this change. We are also proposing to add a new factor for measures where it is not feasible to implement the measure specifications; we would refer to this new factor as Factor 7. Proposed Factors 1 through 7 are as follows:

- Factor 1. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (for example, the measure is topped-out).
- Factor 2. Performance or improvement on a measure does not result in better or the intended patient outcomes.
- Factor 3. A measure no longer aligns with current clinical guidelines or practice.
- Factor 4. A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time

to desired patient outcomes for the particular topic becomes available.

- Factor 5. A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.
- Factor 6. Collection or public reporting of a measure leads to negative or unintended consequences.

• Factor 7. It is not feasible to implement the measure specifications.

We believe these proposed updates would better ensure that we use a consistent approach across our quality reporting and value-based purchasing programs when considering measures for removal, and that they reflect the considerations we have long used when evaluating measures for removal from the ESRD QIP. However, even if one or more of the measure removal factors applies, we might nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could result in poor quality, or in the event that a given measure is statutorily required. Furthermore, consistent with other quality reporting programs, we propose to apply these factors on a case-by-case basis.

We welcome comment on these proposals.

b. Proposed New Measure Removal Factor

In this proposed rule, we are proposing to adopt an additional factor to consider when evaluating measures for removal from the ESRD QIP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the Program.

As we discuss in section IV.A.1 of this proposed rule, with respect to our new "Meaningful Measures Initiative," we are engaging in efforts to ensure that the ESRD QIP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the Program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the Program. We have identified several different types of costs, including, but not limited to: (1) Provider, supplier and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) provider, supplier and clinician cost associated with complying with other quality programmatic requirements; (3) provider, supplier and clinician cost

associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) CMS cost associated with the Program oversight of the measure, including measure maintenance and public display; and (5) provider, supplier and clinician cost associated with compliance with other federal and/ or state regulations (if applicable). For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports Program objectives (for example, informing beneficiary choice). It may also be costly for health care providers to track confidential feedback preview reports and publicly reported information on a measure where we use the measure in more than one Program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools needed to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different Programs.

When these costs outweigh the evidence supporting the continued use of a measure in the ESRD QIP, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ESRD QIP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, removing the measure from the ESRD QIP may better accommodate the costs of Program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We are proposing that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the Program forward in the least burdensome manner possible, while maintaining an appropriately sized set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We are inviting public comment on our proposal to adopt an additional measure removal factor, "the costs associated with a measure outweigh the benefit of its continued use in the Program," beginning with PY 2021.

c. Proposed Removal of Four Reporting Measures

We have undertaken efforts to review the existing ESRD QIP measure set in the context of the Meaningful Measures Initiative described in section IV.A.1 of this proposed rule. Based on that analysis and our evaluation of the Program's measures, we are proposing to remove four measures previously adopted for the ESRD QIP, starting with PY 2021. If these proposals are finalized, facilities would no longer be required to report data specific to these measures beginning with January 1, 2019 dates of service. The four measures we are proposing to remove from the ESRD OIP measure set are:

- Healthcare Personnel Influenza Vaccination.
 - Pain Assessment and Follow-Up.
 - Anemia Management.
 - Serum Phosphorus.

Proposed Removal of the Healthcare Personnel Influenza Vaccination Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Healthcare Personnel Influenza Vaccination reporting measure in the ESRD QIP measure set beginning with PY 2018 because we recognize that influenza immunization is an important public health issue and that vaccinating healthcare personnel against influenza can help to protect healthcare personnel and their patients (79 FR 66206 through 66208). We continue to believe that the Healthcare Personnel Influenza Vaccination measure provides the benefit of protecting patients against influenza. However, our analysis of CY 2016 data indicates that ESRD facility performance on the measure was consistently high; 98 percent of ESRD facilities received the highest possible score on the measure (10 points) and the remaining 2 percent received no score on the measure because they did not report the required data. This finding indicates that influenza vaccination of healthcare personnel in ESRD facilities is a widespread practice and that there is little room for improvement on this measure. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set beginning with PY 2021 under Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying

that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Pain Assessment and Follow-Up Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Pain Assessment and Follow-Up reporting measure beginning with PY 2018 (79 FR 66203 through 66206) because patients with ESRD frequently experience pain that has a debilitating impact on their daily lives, and research has shown a lack of effective pain management strategies in place in dialysis facilities. We continue to believe that effective pain management is an important component of the care received by ESRD patients. However, our analysis of CY 2016 data indicates that with respect to that year, 90 percent of ESRD facilities received the highest possible score on the measure (10 points) and 1 percent of ESRD facilities received no score on the measure. This finding indicates that documentation of pain management using a standardized tool, as well as documentation of a follow-up plan where pain is present, are widespread practices in ESRD facilities and that there is little room for improvement on the measure. Accordingly, we are proposing to remove this measure from the ESRD QIP measure set based on our proposed Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Anemia Management Reporting Measure From the ESRD QIP Measure Set

In the CY 2013 ESRD PPS final rule. we adopted the Anemia Management reporting measure beginning with the PY 2015 ESRD QIP (77 FR 67491 through 67495) because we believe that it is important to monitor hemoglobin levels in patients to ensure that anemia is properly treated. Additionally, the measure's adoption fulfilled the statutory requirement at section 1881(h)(2)(A)(i) of the Act that the ESRD QIP include measures on anemia management that reflect labeling approved by the Food and Drug Administration (FDA) for such management. Additionally, in the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we adopted the NQFendorsed Standardized Transfusion Ratio (STrR) measure beginning with PY 2018 to ensure that patients with ESRD are not negatively affected by

underutilization of ESAs, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions. We stated that there is a strong association between achieved hemoglobin levels and subsequent transfusion events, and that facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices (79 FR 66194). We also noted that the STrR measure meets the requirement at section 1881(h)(2)(A)(i) of the Act for the ESRD QIP to adopt measures of anemia management that reflect the labeling approved by the Food and Drug Administration for such management.

Our analysis of CY 2016 data indicates that ESRD facility performance on the Anemia Management reporting measure was consistently high; 96 percent of ESRD facilities received the highest possible score on the measure (10 points). This finding indicates that facility tracking of hemoglobin values and, as applicable, ESA dosages, is widely performed among ESRD facilities and that there is little room for improvement on the measure.

We are therefore proposing to remove the Anemia Management reporting measure from the ESRD QIP measure set based on Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Proposed Removal of the Serum Phosphorus Reporting Measure From the ESRD QIP Measure Set

In the CY 2014 ESRD PPS final rule, we adopted the Hypercalcemia measure beginning with the PY 2016 ESRD QIP (78 FR 72200 through 72203) as a measure of bone mineral metabolism. Specifically, this measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average. In the CY 2017 ESRD PPS final rule (81 FR 77876 through 77879), we finalized two modifications to the measure's technical specifications, as recommended during the measure maintenance process at the NQF, beginning with PY 2019. First, we added plasma as an acceptable substrate in addition to serum calcium. Second. we amended the denominator definition to include patients regardless of whether any serum calcium values were reported at the facility during the 3month study period. These changes ensure that, beginning with PY 2019, the measure aligns with the NQFendorsed measure.

In the CY 2017 ESRD PPS final rule, we adopted a second measure of bone

mineral metabolism, beginning with PY 2020: The Serum Phosphorus reporting measure (81 FR 77911 through 77912). This measure evaluates the extent to which facilities monitor and report patient phosphorus levels.

While we consider both the Hypercalcemia measure and the Serum Phosphorus measure to be measures of bone mineral metabolism, the two measures track different minerals. Hypercalcemia measures calcium levels and Serum Phosphorus measures phosphorus levels. Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calciumphosphorus dysregulation (81 FR 77911).

As a result of the NQF's 2017 reendorsement of the Hypercalcemia measure, as well as the Hypercalcemia measure's focus on clinical factors that are more directly under the facility's control, we now consider the Hypercalcemia measure to be a superior measure of bone mineral metabolism compared with Serum Phosphorus. In addition, of the two measures, the

Hypercalcemia measure is more focused on outcomes; the Serum Phosphorus is a reporting measure while the Hypercalcemia measure is a clinical measure. Finally, the Hypercalcemia measure is an outcome-based measure specific to the conditions treated with oral-only drugs, which is a statutory requirement for the ESRD QIP measure set. Based on the limited benefit provided to the Program by the Serum Phosphorus measure as well as its reporting burden, we are proposing to remove the Serum Phosphorus reporting measure from the ESRD QIP measure set based on Factor 5 (that is, a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available).

We seek comments on these proposals. We note that we are not proposing any changes to the PY 2021 performance period or performance standards, and we refer readers to the CY ESRD PPS 2018 final rule (82 FR 50778 through 50779) for a discussion of those policies.

2. Estimated Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2021 ESRD QIP

In the CY 2018 ESRD PPS final rule (82 FR 50763 through 50764) we

finalized that for PY 2021, the performance standards, achievement thresholds, and benchmarks for the clinical measures would be set at the 50th, 15th, and 90th percentile, respectively, of national performance in CY 2017, because this would give us enough time to calculate and assign numerical values to those performance standards prior to the beginning of the performance period for that payment year. At this time, we do not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we do not yet have complete data from CY 2017. Nevertheless, we are able to estimate these numerical values based on the most recent data available. In Table 14. we have provided the estimated numerical values for all finalized PY 2021 ESRD QIP clinical measures, and we note that we have not proposed in this proposed rule to remove any of those measures. We will publish updated values for the clinical measures, using CY 2017 data that facilities submitted in the first part of CY 2018, in the CY 2019 ESRD PPS final

TABLE 14—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2021 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

| Measure | Achievement threshold | Benchmark | Performance standard |
|---|-----------------------|-----------|-------------------------|
| Vascular Access Type: | | | |
| Standardized Fistula Rate | 0.518 | 0.752 | 0.628 |
| Long-Term Catheter Rate | 19.23% | 5.47% | 12.02% |
| Kt/V Composite | 91.09% | 98.56% | 95.64% |
| Hypercalcemia | 2.41% | 0.00% | 0.86% |
| Standardized Transfusion Ratio | 1.683 | 0.200 | 0.846 |
| Standardized Readmission Ratio | 1.273 | 0.630 | 0.998 |
| NHSN BSI | 1.598 | 0 | 0.740 |
| SHR measure | 1.249 | 0.670 | 0.967 |
| ICH CAHPS: Nephrologists' Communication and Caring | 57.36% | 78.09% | 67.04% |
| ICH CAHPS: Quality of Dialysis Center Care and Operations | 53.14% | 71.52% | 61.22% |
| ICH CAHPS: Providing Information to Patients | 73.31% | 86.83% | 79.79% |
| ICH CAHPS: Overall Rating of Nephrologists | 49.33% | 76.57% | 62.22% |
| ICH CAHPS: Overall Rating of Dialysis Center Staff | 48.84% | 77.42% | 62.26% |
| ICH CAHPS: Overall Rating of the Dialysis Facility | 52.24% | 82.48% | 66.82% |

Data sources: VAT measures: 2016 CROWNWeb; SRR, STrR, SHR: 2016 Medicare claims; Kt/V: 2016 CROWNWeb; Hypercalcemia: 2016 CROWNWeb; NHSN: 2016 CDC, ICH CAHPS: CMS 2015 and 2016.

In previous rulemaking, we have finalized that if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than they were for that measure in the previous year of the ESRD QIP, then we would substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. In the CY 2017 ESRD PPS final rule, we finalized

an update to that policy because in certain cases, it may be appropriate to re-baseline the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, such that expected infection rates are calculated on the basis of a more recent year's data (81 FR 77886). In such cases, numerical values assigned to performance standards may appear to decline, even though they represent

higher standards for infection prevention. For PY 2021 and future payment years, we propose to continue use of this policy for the reasons explained above.

3. Proposed Change to the Scoring Methodology Previously Finalized for the PY 2021 ESRD QIP

As described in section IV.A.1 of this proposed rule, CMS has established the Meaningful Measures Initiative to help

guide and focus measure development efforts across settings. In order to align the ESRD QIP more closely with the priorities of that initiative, we proposed in section IV.B.1.c of this proposed rule to remove four reporting measures from the ESRD QIP measure set, beginning with PY 2021. In this section, we are proposing to make changes to the measure domains and weights.

a. Proposed Revision To Measure Domains Beginning With the PY 2021 ESRD QIP

To more closely align with the Meaningful Measures Initiative, we are proposing to eliminate the Reporting Domain and to reorganize the Clinical Domain into three distinct domains: Patient & Family Engagement Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), Care Coordination Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), and Clinical Care Domain (currently the Clinical Care Subdomain). Adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Initiative. The proposed Clinical Care Domain would align with the Meaningful Measure Initiative priority to promote effective prevention and treatment of chronic disease. The proposed Patient & Family Engagement Domain would align with the Meaningful Measures Initiative priority to strengthen person and family engagement as partners in their care. The proposed Care Coordination Domain would align with the Meaningful Measures Initiative priority to promote effective communication and coordination of care. We are also proposing to continue use of the Patient Safety Domain. The Patient Safety Domain would align with the Meaningful Measures Initiative priority to make care safer by reducing harm caused in the delivery of care. We are also proposing to eliminate the Reporting Measure Domain from the ESRD QIP measure set, beginning in the PY 2021 Program, because there would no longer be any measures in that domain if our measure removal proposals in section IV.B.1.c of this proposed rule and our proposals in section IV.B.3.b of this proposed rule to reassign the Ultrafiltration Rate, and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively, are finalized.

b. Proposed Revisions to the PY 2021 Domain and Measure Weights Used To Calculate the Total Performance Score (TPS)

We are proposing to update the domain weights to reflect our proposed removal of the Reporting Domain and our proposed reorganization of the Clinical Domain into three distinct domains, as shown in Table 15. We believe that this proposed domain weighting best aligns the ESRD QIP's measure set with our preferred emphasis on clinical outcomes by assigning the two largest weights in the Program to the domains most focused on clinical outcomes (Clinical Care Domain and the Care Coordination Domain). Of those two domains, we are proposing to assign the Clinical Care Domain the highest weight because it contains the largest number of measures. We are proposing to assign the remaining two domains a smaller share of the total performance score (TPS) (both 15 percent) because they are more focused on measures of clinical processes and less on measures of patient outcomes. We continue to believe that the measures in the Patient & Family Engagement and Safety domains address important clinical topics, but we have concluded that placing more weighting on measures more directly tied to clinical outcomes is the most appropriate method to structure the ESRD QIP's measure domains.

We are also proposing to adjust the PY 2021 measure weights that were finalized in the CY 2018 ESRD PPS final rule (82 FR 50781 through 50783), as shown in Table 15. This proposal is also intended to reflect our preferred emphasis on weighting measures that directly impact clinical outcomes more heavily. We also took into consideration the degree to which a facility can influence a measure rate by assigning a higher weight to measures where a facility has greater influence compared to measures where a facility has less influence.

TABLE 15—PROPOSED DOMAIN AND MEASURE WEIGHTING FOR THE PY 2021 ESRD QIP

| Proposed measures/ measure topics by domain | Proposed measure weight as percent of TPS | | |
|---|---|--|--|
| Patient & Family Engage- ment Measure Domain: ICH CAHPS measure | 15.00 | | |
| | 15.00 | | |

TABLE 15—PROPOSED DOMAIN AND MEASURE WEIGHTING FOR THE PY 2021 ESRD QIP—Continued

| Proposed measures/ measure topics by domain | Proposed measure weight as percent of TPS |
|---|---|
| Care Coordination Measure Domain: SRR measure SHR measure Clinical Depression and Follow-Up reporting | 14.00 14.00 |
| measure | 2.00 |
| Clinical Care Measure Do- main: Kt/V Dialysis Adequacy | 30 |
| Comprehensive measureVascular Access Type | 6.00 |
| measure topic * | 6.00 |
| Hypercalcemia measure STrR measure Ultrafiltration Rate re- | 3.00 22.00 |
| porting measure | 3.00 |
| Safety Measure Domain: | 40 |
| NHSN BSI measure NHSN Dialysis Event re- | 9.00 |
| porting measure | 6.00 |
| | 15 |

*The VAT Measure Topic is weighted for each facility based on the number of eligible patients for each of the two measures in the topic, with each measure score multiplied by the respective percentage of patients within the topic to reach a weighted topic score that will be unique for each facility (76 FR 70265, 70275).

As shown in Table 15, we are proposing to decrease the weight of the following measures: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure (18.75 to 15 percent), Kt/V Dialysis Adequacy Comprehensive measure (13.5 to 6 percent), and Vascular Access Type (VAT) measure topic (13.5 to 6 percent). We are also proposing to increase the weights of the following measures: Standardized Readmission Ratio (SRR) measure (11.25 to 14 percent), Standardized Hospitalization Ratio (SHR) measure (8.25 to 14 percent), Clinical Depression and Follow-Up measure (1.66 to 2 percent), Hypercalcemia measure (1.5 to 3 percent), STrR measure (8.25 to 22 percent), and Ultrafiltration reporting measure (1.66 to 3 percent). We are proposing these changes to reflect our continued evaluation of the ESRD QIP's measures and their contribution to the TPS in light of the proposed domain structure and weights as well as the proposed removal of the four reporting

measures. We note that we are not proposing any changes to the two measures included in the Safety Measure Domain: NHSN BSI and NSHN Dialysis Event measures. We continue to believe that the Safety domain appropriately contains these two NHSN measures and we believe their assigned weights—9 percent and 6 percent respectively—reflect the importance that we place on measures of patient safety for the PY 2021 ESRD QIP.

We seek comment on our proposed domain and measure weighting proposals.

Proposals To Update the Eligibility Requirement for Receiving a TPS for a PY and Reassign Measure Weights

In the CY 2017 ESRD PPS final rule (81 FR 77888 through 77889), we finalized that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Domain. We are proposing to revise this policy due to our proposed removal of the Reporting Domain from the ESRD QIP measure set and our proposal to increase the number of domains overall from three to four. We are proposing that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in any two out of the four domains in the ESRD QIP measure set. The proposed approach is consistent with our previously finalized policy because it would allow facilities to receive a TPS with as few as two measure scores. The proposed approach also enables us to maximize the number of facilities that can participate, while ensuring that ESRD facilities are scored on a sufficient number of measures to create a sufficiently-reliable TPS.

Because of this proposed eligibility requirement to receive a TPS, we concluded that we must also consider how to reassign measure weights in those cases where facilities do not receive a score on every measure but receive scores on enough measures to receive a TPS. We considered two alternatives to address this issue: (1) Redistribute the weights of missing measures evenly across the remaining measures (that is, we would divide up the missing measure weights equally across the remaining measures), and (2) redistribute the weights of missing measures proportionately across the remaining measures, based on their weights as a percentage of TPS (that is, when dividing up missing measure weights, we would shift a larger share of the weights to measures with higher assigned weights; measures with lower

weights would gain a smaller portion of the missing measure weights).

While the first policy alternative is administratively simpler to implement, this option would not maintain the Meaningful Measures Initiative priorities in the measure weights as effectively, and therefore, we are proposing the second policy alternative. As discussed earlier, we are proposing an approach for reweighting the domains and measures in the ESRD QIP for PY 2021 based on the priorities identified in the Meaningful Measures Initiative. Under this approach, we are proposing to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. If we adopted the first policy alternative, measures that we consider a lower priority would represent a much larger share of TPS relative to measures that we consider a higher priority, in situations where a facility is missing one or more measure scores. Under the second policy alternative, when a facility is not scored on a measure, the weight of lower priority measures relative to higher priority measures would be more consistent with the weights assigned to the complete measure set. We note that this proposal, if finalized, would be effective for PY 2021; we use the PY 2022 measure set for the following example. If a facility was ineligible to receive a score on all of the measures in both the Clinical Care Measure Domain and the Safety Measure Domain in PY 2022, the weight of the Clinical Depression and Follow-Up Measure the lowest weighted measure remaining in the measure set would increase from 2.5 percent of the TPS to 13.5 percent of the TPS under the first policy alternative and would increase from 2.5 percent of the TPS to 5.6 percent of the TPS under the second policy alternative. Under the same scenario, the weight of the ICH CAHPS measure the highest weighted remaining in the measure set would increase from 15 percent to 26 percent under the first policy alternative and would increase from 15 percent to 33.33 percent under the second policy alternative.

Therefore, based on these considerations, we are proposing that in cases where a facility does not receive a score on one or more measures but receives scores on enough measures to receive a TPS, we would redistribute the weights of any measures for which the facility does not receive a score to the remaining measures proportionately based on their measures weight as a percent of the TPS. This redistribution would occur across all measures, regardless of their domain, and would

be effective beginning PY 2021. We have concluded that this policy would more effectively maintain the Meaningful Measure Initiative's priorities in the ESRD QIP's measure weights in situations where a facility does not receive a score on one or more measures. We believe that this proportional reweighting would ensure ESRD QIP TPSs are calculated in a fair and equitable manner.

We seek comment on this proposal.

4. Proposed Update to the Requirement To Begin Reporting Data for the ESRD OIP

In the CY 2013 ESRD PPS final rule, we finalized our current policy to begin counting the number of months in which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date (77 FR 67512 through 67513). In response to comments suggesting that facilities be required to begin reporting on the first day of the third month after its CCN Open Date, we agreed that a facility needs time to ensure that its systems are in place to report the data, and we adopted policies that would allow new facilities to be exempted from scoring on individual measures based on their CCN Open Date. Despite these policies, we have continued to receive feedback that new facilities need additional time to deploy their information systems and enroll in CROWNWeb and NHSN. This feedback was presented both through the rulemaking process (80 FR 69066), and during the period in which facilities preview their scores. In response to this continued feedback, we have taken another look at our eligibility policies for new facilities, keeping in mind that program requirements have become more complex over time, and have concluded that our existing policy may not provide new facilities with sufficient time to enroll in CROWNWeb and the NHSN, or otherwise prepare to report the data needed for the ESRD QIP.

Accordingly, for PY 2021 and beyond, we are proposing to update this policy. The proposed policy would require facilities to collect data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CCN becomes effective. For example, if a facility has a CCN effective date of January 15, 2019, that facility would be required to begin collecting data for purposes of the ESRD QIP beginning with services furnished on May 1, 2019. The proposed policy would provide facilities with a longer time period than they are given now to

become familiar with the processes for collecting and reporting ESRD QIP data before those data are used for purposes of scoring. We believe this policy appropriately balances our desire to incentivize prompt participation in the ESRD QIP with the practical challenges facing new ESRD facilities as they begin operations.

We welcome public comments on this proposal.

5. Estimated Payment Reduction for the PY 2021 ESRD QIP

Under our current policy, a facility will not receive a payment reduction in connection with its performance under the PY 2021 ESRD QIP if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (1) It performs at the performance standard for each clinical measure; and (2) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2019 reporting measures (82 FR 50787 through 50788).

We were unable to calculate a minimum a TPS for PY 2021 in the CY 2018 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We therefore stated in the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788) that we would publish the minimum TPS for the PY 2021 ESRD QIP in the CY 2019 ESRD PPS final rule.

Based on the estimated performance standards proposed in section IV.B.2 of this proposed rule, we estimate that a facility must meet or exceed a minimum TPS of 57 for PY 2021. For all of the clinical measures, these data come from CY 2017. We are proposing that a facility that achieves a TPS below the minimum TPS that we set for PY 2021 would receive payment reduction based on the estimated TPS ranges indicated in Table 16.

TABLE 16—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2021 BASED ON THE MOST RECENTLY AVAILABLE DATA

| Total performance score | Reduction (%) |
|-------------------------|---------------|
| 100–57 | 0 |
| 56–47 | 0.5 |
| 46–37 | 1.0 |
| 36–27 | 1.5 |
| 26–0 | 2.0 |

We intend to finalize the minimum TPS for PY 2021, as well as the payment reduction ranges for that PY, in the CY 2019 ESRD PPS final rule.

We see comment on these proposals.

6. Data Validation Proposals for PY 2021 and Subsequent Years

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: The CROWNWeb pilot data validation study (OMB Control Number 0938–1289) and the NHSN dialysis event validation study (OMB Control Number 0938–1340).

Since the PY 2016 ESRD QIP, we have validated data submitted to CROWNWeb for each payment year by sampling no more than 10 records from 300 randomly selected facilities (78 FR 72223 through 72224). In the CY 2018 ESRD PPS final rule, we finalized that for PY 2020, we would continue validating these data using the same methodology, but also finalized that we would deduct 10 points from a facility's TPS for PY 2020 if the facility was selected for validation but did not submit the requested records within 60 calendar days of receiving a request (82 FR 50766 through 50767).

Since we issued the CY 2018 ESRD PPS final rule, we have considered whether it is appropriate to continue to refer to this validation of CROWNWeb data as a study. We analyzed the CROWNWeb data that we used for purposes of the PY 2016 validation study to determine how reliable the current methodology is, and our analysis showed an overall match rate of 92.2 percent among the facilities selected for participation. Additionally, based on our statistical analyses, we have concluded that the validation study is well-powered when we sample 10 records per facility from 300 facilities, meaning that a validation study implemented with those sampling requirements will meet our needs when assessing the accuracy and completeness of facilities' CROWNWeb data submissions.

This analysis indicates that our validation methodology produces reliable results and can be used to ensure that accurate ESRD QIP data are reported to CROWNWeb. Therefore, we are proposing to validate the CROWNWeb data submitted for the ESRD QIP, beginning with CY 2019 data submitted for PY 2021, using the methodology we first adopted for the PY 2016 ESRD QIP and updated for the PY 2020 ESRD QIP. Under this methodology, we would sample no more than 10 records from 300 randomly selected facilities each year, and we would deduct 10 points from a

facility's TPS if the facility was selected for validation but did not submit the requested records.

With respect to data submitted to the NSHN, we have been developing and testing a protocol for validating those data on a statistically relevant scale. For PY 2020, our methodology for this feasibility study is to randomly select 35 facilities and require that each of those facilities submit 10 patient records covering 2 quarters of data reported in CY 2018. Our selection process targets facilities for NHSN validation by identifying which facilities that are at risk for under-reporting. For additional information on this methodology, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

We have continued to work with the Centers for Disease Control and Prevention (CDC) to determine the most appropriate sample size for achieving reliable validation results through this NSHN dialysis event validation study. Based on recent statistical analyses conducted by the CDC, we have concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. This sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on these results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP is accurate, we are proposing to increase the sample sizes used for the NHSN dialysis event validation study, over a 2 year period, to 300 facilities and 20 records per quarter for each of the first 2 quarters of the CY for each facility selected to participate in the study.

Specifically, for PY 2021, we are proposing to increase the number of facilities that we would select for validation to 150, and then for PY 2022, to increase that number to 300. With respect to the number of patient records that each selected facility would be required to submit to avoid a 10 point deduction to its TPS for that payment year, we are proposing that for both PY 2021 and PY 2022, each selected facility must submit 20 patient records per quarter for each of the first 2 quarters of the CY, within 60 calendar days of receiving a request. We are also proposing to continue targeted validation.

We seek comments on these proposals. We also seek comments on potential future policy proposals that would encourage accurate, comprehensive reporting to the NHSN, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold,

introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on NHSN reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

C. Proposed Requirements for the PY 2022 ESRD QIP

1. Proposed Continuing and New Measures for the PY 2022 ESRD QIP

If our proposal to remove four measures beginning with the PY 2021 ESRD QIP is finalized, the PY 2021 ESRD QIP measure set would have 12 measures. In the CY 2013 ESRD PPS final rule, we finalized that once a quality measure is selected and finalized for the ESRD QIP through rulemaking, the measure would continue to remain part of the Program for all future years, unless we remove or replace it through rulemaking or notification (if the measure raises potential safety concerns) (77 FR 67475). In addition to continuing all of the measures included in the PY 2021 ESRD QIP, we are proposing to adopt two new measures beginning with the PY 2022 ESRD QIP: Percentage of Prevalent Patients Waitlisted clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities reporting

a. Proposed Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure

We are proposing to add one new transplant clinical measure to the ESRD QIP measure set beginning with PY 2022: (1) Percentage of Prevalent Patients Waitlisted (PPPW). The proposed new PPPW measure would align the ESRD QIP more closely with a Meaningful Measures Initiative priority area—increased focus on effective communication and coordination. The proposed measure assesses the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist.

Background

The benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD are well established. Although no clinical trials comparing the two have ever been done due to ethical considerations, a large number of observational studies have been conducted demonstrating improved

survival and quality of life with kidney transplantation. ¹¹ Despite the benefits of kidney transplantation, the total number of transplants performed in the U.S. has stagnated since 2006. ¹² There is also wide variability in transplant rates across ESRD networks. ¹³ Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, a measure to encourage facilities to coordinate care with transplant centers to waitlist patients is warranted.

This measure emphasizes shared accountability between dialysis facilities and transplant centers.

Data Sources

The proposed PPPW measure uses CROWNWeb data to calculate the denominator, including the risk adjustment and exclusions. The Organ Procurement and Transplant Network (OPTN) is the data source for the numerator (patients who are waitlisted.) The OPTN is a public-private partnership established by the National Organ Transplant Act in 1984. The private nonprofit organization, United Network for Organ Sharing (UNOS) handles administration of the waitlist under a contract with the federal government. The Nursing Home Minimum Dataset and Questions 17u and 22 on the Medical Evidence Form CMS-2728 are used to identify ESRD patients who were admitted to a skilled nursing facility (SNF) because those patients are excluded from the measure. A separate CMS file that contains final action claims submitted by hospice providers is used to identify ESRD patients who have been admitted to hospice because those patients are also excluded from the measure.

Outcome

The PPPW measure tracks the percentage of patients attributed to each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas transplant waitlist. The measure is a directly standardized percentage, in that each facility's percentage of kidney transplant patients

on the kidney transplant waitlist is based on the number of patients one would expect to be waitlisted for a facility with patients of similar age and co-morbidities.

Cohort

The PPPW measure includes ESRD patients who are under the age of 75 on the last day of each month and who are attributed to the dialysis facility. We create a treatment history file using a combination of Medicare dialysis claims, the Medical Evidence Form CMS-2728, and data from CROWNWeb as the data source for the facility attribution. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or until the measurement period ends. For each patient, a new record is created each time he or she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. Each patient-month is assigned to only one facility. A patient could be counted up to 12 times in a 12-month reporting period, and home dialysis is included.

Inclusion and Exclusion Criteria

The PPPW measure excludes patients 75 years of age or older on the last day of each month. Additionally, patients who are admitted to a SNF or hospice during on the date that the monthly count takes place are excluded from the denominator for that month. An eligible monthly patient count takes place on the last day of each month during the performance period.

Risk Adjustment

The PPPW measure is adjusted for patient age. The measure is a directly standardized percentage, in the sense that each facility's percentage of patients on the waitlist is adjusted to the national age distribution. Further information on the risk adjustment model can be found in the PPPW Methodology Report (https:// www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061 Technical Specifications.html). We assume a logistic regression model for the probability that a prevalent patient is waitlisted.

2017 Measures Application Partnership Review

We submitted the PPPW measure to the Measures Application Partnership in 2017 for consideration as part of the prerulemaking process, and Measures Application Partnership's final

¹¹Tonelli M, Wiebe N, Knoll G, et al. Systematic review: Kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplantation 2011 Oct; 11(10): 2093– 2100

¹² Schold JD, Buccini LD, Goldfarb DA, et al. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. Clin J Am Soc Nephrol. 2014 Oct 7; 9(10):1773–80.

¹³ Patzer RE, Plantinga L, Krisher J, Pastan SO. Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities. Am J Transplant. 2014 Jul; 14(7):1562–72.

recommendations may be found at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

The Measures Application Partnership expressed conditional support for the PPPW measure for inclusion in the ESRD QIP. The Measures Application Partnership acknowledged that the measure addresses an important quality gap in dialysis facilities, but discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality. The Measures Application Partnership also noted that there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlisting processes and requirements. The Measures Application Partnership also acknowledged that a patient's suitability to be waitlisted may not be within the control of a dialysis facility or transplant centers. The Measures Application Partnership also noted the need to ensure that the measure is appropriately risk-adjusted and recommended that CMS explore whether it would be appropriate to adjustment the measure for social risk factors and proper risk model performance. The Measures Application Partnership conditionally supported the measure with the condition that CMS submit it to the NQF for consideration of endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by NQF's Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended that as part of the endorsement process, the NQF examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns.

In response to these recommendations, we have submitted the measure to the NQF for consideration of endorsement, and our understanding is that it will be evaluated by all of the committees that the Measures Application Partnership suggested. We note further that access to transplantation is a known area of disparity and has a known performance gap, and the Measures Application Partnership coordinating committee

expressed strong support for the measure.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972.

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure to the NQF for consideration of endorsement, we propose to adopt the PPPW measure beginning with the PY 2022 ESRD QIP. We note also that there are currently no NQF-endorsed transplant measures that we could have considered, and that we believe we should adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We welcome comments on this proposal.

b. Proposed New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Reporting Measure

We are proposing to adopt the New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure for the ESRD QIP measure set, beginning with PY 2022. The MedRec measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the ESRD patient population because those patients typically take a large number of medications. Inclusion of the MedRec measure in the ESRD QIP measure set would align with the Meaningful Measure Initiative priority area of making care safer by reducing harm caused by care delivery.

Medication management is a critical safety issue for all patients, but especially for patients with ESRD, who are often prescribed 10 or more medications simultaneously, take an average of 17 to 25 doses per day, have numerous comorbid conditions, have multiple healthcare providers and prescribers, and undergo frequent medication regimen changes. 14 Medication-related problems contribute significantly to the approximately \$40 billion in public and private funds spent

annually on ESRD care in the U.S.; for patients with chronic kidney disease alone, this figure is \$10 billion. ¹⁵ We believe that medication management practices focusing on medication documentation, review, and reconciliation could systematically identify and resolve medication-related problems, improve ESRD patient outcomes, and reduce total costs of care.

Data Sources

The proposed MedRec measure is calculated using administrative claims and electronic clinical data from CROWNWeb, and facility medical records. For additional information on the measure, we refer readers to the measure steward's website; the Kidney Care Quality Alliance (KCQA): http:// kidneycarepartners.com/wp-content/ uploads/2014/11/tbKCQA NQF endorsedSpecs10-26-17.pdf. The KCQA is funded by Kidney Care Partners (KCP), a coalition of patient advocates, dialysis professionals, care providers, and manufacturers, and was established in 2005 as an independent organization for the purpose of developing quality measures for use in the dialysis setting of care.

Outcome

The outcome of the MedRec measure is the provision of medication reconciliation services and their documentation by an eligible professional for patients attributed to dialysis facilities each month.

Cohort

The MedRec measure includes all patients attributed to a dialysis facility during each month of the performance period. The numerator is the number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period. The denominator statement is the total number of eligible patient-months for all patients attributed to a dialysis facility during the reporting period.

Inclusion and Exclusion Criteria

The MedRec measure excludes incenter patients who receive less than 7 hemodialysis treatments in the facility during the reporting month.

Risk Adjustment

The MedRec measure is not riskadjusted because it is process measure.

¹⁴Cardone KE, Bacchus S, Assimon MM, Pai AB, Manley HJ. Medication-related problems in CKD. Adv Chronic Kidney Dis. 2010;17(5):404–412.

¹⁵ Parker WM and Cardone KE. Medication Management Services in a Dialysis Center: Patient and Dialysis Staff Perspectives. Albany College of Pharmacy and Health Services. January 2015. Available at: http://www.acphs.edu. Accessed March 22, 2016.

2017 Measures Application Partnership Review

We submitted the MedRec measure to the Measures Application Partnership in 2017 for consideration as part of the prerulemaking process, and the Measures Application Partnership addressed the measure in its February 2018 Hospital Workgroup report. 16 The Measures Application Partnership supported the measure for the ESRD QIP, noting that the measure is NQF-endorsed and addresses both patient safety and care coordination. The Measures Application Partnership also noted that the topic of medication reconciliation is currently a gap area in the ESRD QIP's measure set and that the measure has broad support across stakeholders. The Measures Application Partnership emphasized that medication reconciliation is an important issue for ESRD patients who see multiple clinicians and may require numerous medications. The Measures Application Partnership noted that administration of the wrong medication can have grave consequences for an ESRD patient.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to the Measures Application Partnership's website at: https://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications Partnership.aspx.

We agree with the Measures Application Partnership's assessment that the MedRec measure is appropriate for the ESRD QIP because medication reconciliation is currently a gap area in the Program's measure set and is an important issue for ESRD patients who receive care from multiple clinicians and providers and may require numerous medications. ESRD patients can be significantly harmed by medication administration errors. We continue to believe that care coordination is a critical quality improvement topic. We therefore, propose to adopt the MedRec measure beginning with the PY 2022 ESRD QIP and to place the measure into the Patient Safety Domain. We note further that, as required by section 1881(h)(2)(B)(i) of the Act, CMS is required to use endorsed measures in the ESRD QIP unless the exception at section 1881(h)(2)(B)(ii) of the Act applies. The MedRec measure is endorsed by NQF as #2988.

2. Proposed Performance Period for the PY 2022 ESRD OIP

We propose to establish CY 2020 as the performance period for the PY 2022 ESRD QIP for all measures. We continue to believe that a 12-month performance period provides us sufficiently reliable quality measure data for the ESRD QIP.

We welcome comment on this proposal.

3. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2022 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act provides that "the Secretary shall establish performance standards with respect to measures elected . . . for a performance period with respect to a year." Section 1881(h)(4)(B) of the Social Security Act (the Act) further provides that the "performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary." We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction.

a. Proposed Performance Standards, Achievement Thresholds, and Benchmarks for Clinical Measures in the PY 2022 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we are proposing for PY 2022 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures (including the proposed PPPW measure) at the 50th, 15th, and 90th percentile, respectively, of the national performance in CY 2018. We are also proposing to apply these performance standards to all clinical measures we use for the ESRD QIP in future payment years. We welcome comment on these proposals.

At this time, we do not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures because we do not yet have data from CY 2018 or the first period of CY 2019. We intend to publish these numerical values, using data from CY 2018 and the first portion of CY 2019, in the CY 2019 ESRD PPS final rule.

b. Proposed Performance Standards for the PY 2022 Reporting Measures

In the CY 2016 ESRD PPS final rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up reporting measure (79 FR 66209). In the CY 2017 ESRD PPS final rule, we finalized performance

standards for the Ultrafiltration Rate reporting measure (81 FR 77916) and the NHSN Dialysis Event reporting measure (81 FR 77916). We propose to continue use of these performance standards for these reporting measures for the PY 2022 and future payment years.

For the proposed MedRec reporting measure, we propose to set the performance standard for PY 2022 and future payment years as successfully reporting the following data elements for the measure to CROWNWeb, for each qualifying patient, on a monthly basis, during the performance period: (1) The date that the facility completed the medication reconciliation, (2) the type of clinician who completed the medication reconciliation, and (3) the name of the clinician.

We welcome comments on these proposals.

- 4. Proposals for Scoring the PY 2022 ESRD QIP and Subsequent Years
- a. Proposal To Score Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). We propose to use this methodology for scoring achievement for each clinical measure, including the proposed PPPW measure, for the PY 2022 ESRD QIP and for future program years.

b. Proposal To Score Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). For the PY 2022 ESRD QIP, we propose to continue that policy, defining the improvement threshold as the facility's performance on the measure during the baseline period (which for PY 2022, would be CY 2019). The facility's improvement score would be calculated by comparing its performance on the measure during CY 2020 (the proposed performance period) to the improvement threshold and benchmark. We also propose to use this same methodology for scoring the PPPW measure proposed in section IV.C.1.a of this proposed rule. Finally, we propose to continue this policy for subsequent years of the ESRD QIP.

c. Scoring Facility Performance on Reporting Measures

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression

¹⁶ Available at: https://www.qualityforum.org/ Publications/2018/02/2018_Considerations_for_ Implementing_Measures_Final_Report_-_ Hospitals.aspx.

Screening and Follow-Up reporting measures in the ESRD QIP (79 FR 66210 through 66211). In the CY 2017 ESRD PPS final rule, we finalized policies for scoring performance on the Ultrafiltration Rate reporting measure (81 FR 77917). We propose to continue use of these policies for the two continuing reporting measures for the PY 2022 ESRD QIP and subsequent years.

For the PY 2022 ESRD QIP, we propose to score facilities with a CCN Open Date before January 1st of the performance period year (which, for the PY 2022 ESRD QIP, would be 2020) on the proposed MedRec measure using a formula similar to the one previously finalized for the Ultrafiltration Rate reporting measure (81 FR 77917): ((# patient-months successfully reporting data)/(# eligible patient-months)*12)–2)

As with the Ultrafiltration Rate reporting measure, we would round the result of this formula (with half rounded up) to generate a measure score from 0–10. We also propose to score facilities

using this methodology for subsequent years of the ESRD QIP.

We welcome public comment on all of these scoring proposals.

d. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We are proposing to use this scoring methodology for the PY 2022 ESRD QIP and subsequent years.

We welcome comments on this scoring proposal.

5. Proposals for Weighting the Measure Domains, and for Weighting the TPS for PY 2022

For PY 2022, we are proposing to continue use of the domain weights proposed for PY 2021 in section IV.B.3 of this proposed rule, and to update the individual measure weights in the Care Coordination Domain and Safety Domain to reflect the introduction of one new proposed measure in each of

those domains. We are proposing to assign the proposed PPPW measure to the Care Coordination Domain, with a weight of 4 percent of the TPS. To accommodate the addition of the PPPW measure to the Care Coordination Domain without having to adjust the domain's overall weight, we are proposing to reduce the weight of two continuing measures in the Care Coordination Domain as follows: The SRR measure from 14 to 12 percent and the SHR measure from 14 to 12 percent. We are proposing to assign the proposed MedRec measure to the Safety Domain, with a weight of 4 percent of the TPS (see Table 17). To accommodate the addition of the new MedRec measure to the Safety Domain without having to adjust the domain's overall weight, we are proposing to reduce the weight of two continuing measures in the Safety Domain as follows: The NHSN BSI clinical measure from 9 to 8 percent and the NHSN Dialysis Event measure from 6 to 3 percent. To assign these proposed measure weights, we used the same rationale as proposed for PY 2021.

TABLE 17—PROPOSED REVISIONS TO MEASURE WEIGHTS FOR THE PY 2022 ESRD QIP

| Measures/measure topics by subdomain | Measure weight within the domain (proposed for PY 2022) | Measure weight as percent of TPS (proposed for PY 2022) | |
|--|---|---|--|
| CARE COORDINATIO | ON MEASURE DOMAIN | | |
| SRR measure | 40.00% | 12.00%. 12.00. 4.00. 2.00. 30% of TPS. | |
| SAFETY MEA | SURE DOMAIN | | |
| MedRec measure NHSN BSI clinical measure NHSN Dialysis Event reporting measure | 26.67 53.33 20.00 | 4.00. 8.00. 3.00. | |
| TOTAL: SAFETY MEASURE DOMAIN | 100% of Safety Measure Domain. | 15% of TPS. | |

In section IV.B.3.b of this proposed rule, we propose that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in two of the four measure domains. If that proposal is finalized, we would apply it to PY 2022 and subsequent payment years.

We seek comments on these proposals.

6. Eligibility Proposals for the PY 2022 ESRD QIP and Subsequent Payment Years

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period (77 FR 67510 through 67512). We propose to continue use of these minimum data policies for the PY 2022 ESRD QIP measure set and in subsequent years. We are also proposing to use these same minimum data policies for the proposed PPPW measure and proposed MedRec measure for the PY 2022 ESRD QIP and subsequent years.

We seek comment on these proposals.

7. Payment Reductions for the PY 2022 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the

application of the scoring methodology results in an appropriate distribution across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For additional information on payment reduction policies, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788).

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. In the CY 2020 ESRD PPS proposed rule, we will propose the minimum TPS, based on CY 2018 data.

- D. Proposed Requirements Beginning With the PY 2024 ESRD QIP
- 1. Proposed New Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Clinical Measure

We are proposing to add one new transplant measure to the ESRD QIP measure set beginning with PY 2024: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). The proposed new SWR measure would align the ESRD QIP more closely with the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The SWR Measure assesses the number of patients who are placed on the transplant waitlist or receive a living donor kidney within one year of the date when dialysis is initiated. We believe this measure would encourage facilities to more rapidly evaluate patients for transplant and coordinate the waitlisting of those patients. 17 Because the proposed SWR measure is limited to patients in their first year of dialysis, it is more limited in scope than the proposed PPPW measure, which includes patients who have been on dialysis for longer than 1 year. We are proposing to introduce the SWR measure for PY 2024 rather than PY 2022 because the proposed SWR measure is calculated using 3 years of data.

Data Sources

The SWR Measure is calculated using administrative claims and electronic clinical data. CROWNWeb is the primary source used to attribute patients to dialysis facilities and dialysis claims are used as an additional source. Information regarding onset of ESRD, the first ESRD treatment date, death, and transplant is obtained from CROWNWeb (including the Medical Evidence Form CMS–2728 and the Death Notification Form CMS–2746) and Medicare claims, as well as the Organ Procurement and Transplant Network.

Outcome

The SWR Measure tracks the number of incident patients attributed to the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Similar to the PPPW measure, the SWR measure emphasizes shared accountability between dialysis facilities and transplant centers.

Cohort

The SWR measure includes patients under the age of 75 and attributed to the dialysis facility using CROWNWeb data and Medicare claims who are listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Patients are attributed to the dialysis facility listed on the Medical Evidence Form CMS—2728.

Inclusion and Exclusion Criteria

The SWR measure excludes patients at the facility who were 75 years of age or older at initiation of dialysis and patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis. Additionally, patients who are admitted to a SNF or hospice at the time of initiation of dialysis are excluded.

Risk Adjustment

The SWR measure is adjusted for incident comorbidities and age. Incident comorbidities were selected for adjustment into the SWR model based on demonstration of a higher associated mortality (hazard ratio above 1.0) and statistical significance (p-value in first year mortality model). More details about the risk adjustment model can be found in the SWR Methodology Report (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_Technical Specifications.html).

2017 Measures Application Partnership Review

We submitted the SWR measure to the Measures Application Partnership in 2017 for consideration as part of the prerulemaking process.

In its report (available on its website at: http://www.qualityforum.org/
WorkArea/linkit.aspx?LinkIdentifier=
id&ItemID=86972), the Measures
Application Partnership acknowledged that the SWR measure addresses an important quality gap for dialysis facilities and discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality.

The Measures Application Partnership also noted there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlist processes and requirements. The Measures Application Partnership also acknowledged concerns and public comment about the locus of control of the measure, where dialysis facilities may not be able to as adequately influence a patient's suitability to be waitlisted as well as the transplant center. The Measures Application Partnership also noted the need to ensure the measure is appropriately risk-adjusted and recommended the exploration of adjustment for social risk factors and proper risk model performance. The Measures Application Partnership ultimately conditionally supported the measure with the condition that it is submitted for NQF review and endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by the NQF Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended the endorsement process examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns. Our understanding is that the NQF endorsement process covers all of the Measure Application Partnership's conditions, and we have submitted the measure for endorsement.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure for NQF endorsement, we propose to adopt the SWR measure beginning with the PY 2024 ESRD QIP. We also propose to place this measure in the Transplant Waitlist measure topic in the Care Coordination Domain, along with the PPPW measure proposed in section IV.C.1.a of this proposed rule, and to score the two measures accordingly as a measure topic. We note also that there

are currently no NQF-endorsed

¹⁷ Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. "Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis1." Transplantation 74.10 (2002): 1377–1381; Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., Leichtman, A. B & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311–1317.

transplant measures that we could have considered, and we believe that we should adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We welcome comments on these proposals.

2. Proposed Performance Period for the SWR Measure

Because the SWR measure is calculated using 36 months of data, we propose to establish a 36-month performance period for the proposed SWR measure. With respect to PY 2024 ESRD QIP, this period would be CY 2019 through 2021. We believe that a 36-month performance period for the SWR measure would enable us to calculate sufficiently reliable measure data for the ESRD QIP.

a. Proposed Performance Standards. Achievement Thresholds, and Benchmarks for the SWR Measure in the PY 2024 ESRD QIP

If our proposal in section IV.D.1 of this proposed rule is finalized, then we would score the proposed SWR measure using a 36-month performance period for purposes of achievement and a corresponding 36-month baseline period for purposes of improvement. For the PY 2024 ESRD QIP, these periods would be CY 2017 through 2019 for achievement and CY 2018 through 2020 for improvement.

At this time, we do not have the necessary data to assign numerical values to the performance standards for the SWR measure, because we do not yet have data from CY 2017 through CY 2020.

V. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and **Supplies (DMEPOS) Competitive** Bidding Program (CBP)

A. Background

Section 1847(a) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs in competitive bidding areas (CBAs) throughout the United States (U.S.) for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The competitive bidding programs of the Medicare Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding

Program (CBP), mandated by section 1847(a) of the Act, are collectively referred to as "DMEPOS CBP". A final rule published on April 10, 2007 in the Federal Register, titled "Competitive Acquisition for Certain DMEPOS and Other Issues", (72 FR 17992), referred to as "2007 DMEPOS final rule" established competitive bidding programs for certain Medicare Part B covered items of DMEPOS throughout the U.S. The competitive bidding programs, which were phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services. Section 1847(a)(2) of the Act describes the items and services subject to the DMEPOS CBP:

- · Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act.
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DMEPOS CBP was modeled after successful demonstration programs from the late 1990s and early 2000s, discussed in the proposed rule published on May 1, 2006 in the Federal Register, titled "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues' (71 FR 25654) referred to as "2006 DMEPOS proposed rule". We received substantial advice in the development of the DMEPOS CBP from the Program Advisory and Oversight Committee (PAOC), which was mandated through section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, to establish a committee to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS CBP, taking into account the needs of small providers.
- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.
- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.

• The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

As authorized under section 1847(c)(2) of the Act, the PAOC members were appointed by the Secretary of the Department of Health and Human Services (the Secretary) and represented a broad mix of relevant industry, consumer, and government parties. The representatives had expertise in a variety of subject matter areas, including DMEPOS, competitive bidding methodologies and processes, and rural and urban marketplace dynamics.

In the DMEPOS CBP, suppliers bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, under several different product categories. Section 1847(a)(1)(B) and (D) of the Act mandated the phase in of the DMEPOS CBP in nine of the largest MSAs (Round 1), followed by 91 additional large MSAs (Round 2), and finally in additional areas, which do not necessarily need to be tied to MSAs. Round 1 and Round 2 CBAs that included more than one state have been subdivided into state-specific CBAs. The CBP is currently operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the CBP has not yet been phased in, including approximately 275 MSAs. In addition, CMS phased in a national mail order program for diabetic testing supplies in 2013. In the Round 1 2017 and Round 2 Recompete competitions, the product categories currently include: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies; Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive pressure airway devices, and respiratory assist devices); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies. Since there are multiple items in each product category, a "composite" bid is calculated for each supplier to determine which supplier's bids would result in the greatest savings

to Medicare for the product category. A supplier's composite bid for a product category is calculated by multiplying a supplier's bid for each item in a product category by the item's weight and taking the sum of these numbers across items. The weight of an item is based on the annual utilization of the individual item compared to other items within that product category based on recent Medicare national claims data. Item weights are used to reflect the relative market importance of each item in the product category. Item weights ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier. The sum of each supplier's weighted bids for every item in a product category is the supplier's composite bid for that product category.

Each supplier submits a bid amount for each item in the product category, and multiple contracts must be awarded for each product category in each CBA. Section 1847(b)(5) of the Act mandates a single payment amount (SPA) for each item based on winning bids from multiple suppliers, so various options for calculating the SPA were addressed in the 2006 DMEPOS proposed rule (71 FR 25679). The methods of using the minimum winning bid amount for each item, the maximum winning bid amount for each item, the median of the winning bid amounts for each item, and an average adjusted price based on the method used during the demonstrations were considered during this rulemaking. The SPA calculation method using the median of the winning bids was finalized in the 2007 DMEPOS final rule (72 FR 18044) based on the rationale that the median of winning bids represents the bid amounts of the winning suppliers as a whole, whereas the minimum and maximum bids did not; it is a simpler method than the average adjusted price method; and it is consistent with the longstanding Medicare payment rules for DMEPOS that established allowed payment amounts based on average reasonable charges rather than minimum or maximum charges.

To implement section 522(a) of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), we published a final rule on November 4, 2016 in the **Federal Register**, titled "End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and

Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model' (81 FR 77834), referred to as "2016 ESRD PPS final rule".

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of MACRA, requires bidding entities to secure a bid surety bond by the deadline for bid submission. Section 1847(a)(1)(G) of the Act provides that, with respect to rounds of competitions under section 1847 of the Act beginning not earlier than January 1, 2017 and not later than January 1, 2019, a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of \$50,000 to \$100,000, in a form specified by the Secretary consistent with paragraph (H) of section 1847(a)(1) of the Act, and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). We believe that section 522(a) of MACRA was drafted under the assumption that the next round of competitive bidding would have been implemented at some point between January 1, 2017 and January 1, 2019. We have interpreted section 522(a) of MACRA as applying to the next round of competitive bidding even though the next round of competition will begin after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidding entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amount(s) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidding entity does not meet the bid bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for such product category and area. As aforementioned,

this requirement was implemented as part of the CY 2016 ESRD PPS final rule (81 FR 77834), so § 414.412(h) now requires that bidding entities obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for the product category/CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. Further detailed conditions of the surety bonds were also clarified in the final rule (81 FR 77931). The bid bond requirement is mentioned here in the background section of this proposed rule because bid bond forfeiture is tied to composite bids under the DMEPOS CBP, and this rule proposes to change how composite bids are defined and to implement lead item pricing under the DMEPOS CBP.

Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. The DMEPOS CBP also includes provisions to ensure beneficiary access to quality DMEPOS items and services. Section 1847(b)(2)(A) of the Act directs the Secretary to award contracts to entities only after a finding that the entities meet applicable quality and financial standards and beneficiary access to a choice of multiple suppliers in the area is maintained, that is, more than one contract supplier is available for the product category in the area.

Sections 1847(b)(6)(Å)(i) and (b)(6)(A)(ii) of the Act provide that payment will not be made under Medicare Part B for items and services furnished under the CBP unless the supplier has submitted a bid to furnish those items and has been awarded a contract. Therefore, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract. In past rounds of

competition, CMS has allowed a 60-day bidding window for suppliers to prepare and submit their bids. Our regulation at § 414.412 specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated and contracts are awarded to qualified suppliers in accordance with the requirements of section 1847(b)(2) of the Act and § 414.414, which specifies conditions for awarding contacts. Under the Round 2 and Round 1 Recompete competitions, 92 percent of suppliers accepted contract offers at the SPAs set through the competitions. In addition, CMS reviewed all contract suppliers based on financial standards when evaluating their bids. This process includes review of tax records, credit reports, and other financial data, which leads to the calculation of a score, similar to processes used by lenders when evaluating the viability of a company. All contract suppliers met the financial standards established for the program. Before awarding contracts, each bid is screened and evaluated to ensure that it is bona fide so that CMS can verify that the supplier can provide the product to the beneficiary for the bid amount, and those that fail are excluded from the competition. Approximately 94 percent of bids screened as part of the Round 2 and Round 1 Recompete competitions were determined to be bona fide.

Section 1847(b)(6)(D) of the Act requires that appropriate steps be taken to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS CBP. We have established a

number of provisions to ensure that small suppliers are given an opportunity to participate in the DMEPOS CBP. For example, under § 414.414(g)(1)(i), we have established a 30 percent target for small supplier participation; thereby ensuring efforts are made to award at least 30 percent of contracts to small suppliers. Also, CMS worked in coordination with the Small Business Administration and based on advice from the PAOC to develop an appropriate definition of "small supplier" for this program. Under § 414.402, a small supplier is one that generates gross revenues of \$3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. Under § 414.418, small suppliers may join together in "networks" in order to submit bids that meet the various program requirements. A majority of the bids used in establishing SPAs come from small suppliers with a history of furnishing items in the CBAs.

B. Current Method for Submitting Bids and Selecting Winners

In the DMEPOS CBP, CMS awards contracts to suppliers for furnishing multiple items and services needed in a given CBA that fall under a product category (for example, respiratory equipment). The product categories are mostly large and include multiple items used for different purposes (for example, the respiratory equipment category includes oxygen equipment and positive pressure airway devices and multiple related accessories) based on past feedback from stakeholders to promote easy access for beneficiaries and referral agents to receive all items

in a product category from one location, and to prevent instances where a supplier wins a contract for one product category but loses the competitions for several other product categories. Because multiple bids for individual items are submitted when competing to become a contract supplier for the product category of items and services as a whole, it is necessary to calculate a composite bid for each bidding supplier to determine the lowest bids for the category as a whole. In accordance with § 414.402, a composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Using a composite bid is a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category.

In order to compute a composite bid, a weight must be applied to each item in the product category. The weight of an item is based on the beneficiary utilization or demand of the individual item compared to other items within that product category based on historic Medicare claims. Item weights are used to reflect the relative market importance of each item in the product category. Table 18 depicts the calculation of the item weights for a supplier's bid. The expected volume for items A, B, and C are 5, 3, and 2 units, respectively, for a total volume of 10 units. The item weight for item A is 0.5 (5/10), the weight for item B is 0.3 (3/10), etc. The total item weight for the supplier's bid is 1.

TABLE 18—ITEM WEIGHTS

| Item | Α | В | С | Total |
|-------|-----|-----|-----|-------|
| Units | 5 | 3 | 2 | 10 |
| | 0.5 | 0.3 | 0.2 | 1 |

The composite bid for a supplier equals the item weight multiplied by the item bid summed across all items in the product category. For example, supplier 1 bid \$1.00 for item A, \$4.00 for item B and \$1.00 for item C. The composite

bid for Supplier 1 = (0.5 * \$1.00) + (0.3 * \$4.00) + (0.2 * \$1.00) = 1.90. Table 19 shows the expected cost of the bundle based on each supplier's bids. The expected costs are directly proportional to the composite bids; the factor of

proportionality is equal to the total number of units (10) in the product category. The composite bid is used to determine the expected costs for all of the items in the product category based upon expected volume.

TABLE 19—COMPOSITE BIDS BY SUPPLIER

| ltem | А | В | С | Composite bid | Product category bid (cost of bundle) |
|----------------|--------|--------|--------|---------------|--|
| Units | 5 | 3 | 2 | | |
| Item weight | 0.5 | 0.3 | 0.2 | | |
| Supplier 1 bid | \$1.00 | \$4.00 | \$1.00 | \$1.90 | \$19.00 |
| Supplier 2 bid | 3.00 | 5.00 | 3.00 | 3.60 | 36.00 |

| Item | А | В | С | Composite bid | Product category bid (cost of bundle) |
|-----------------|------|------|------|---------------|---------------------------------------|
| Supplier 3 bid | 3.00 | 4.00 | 3.00 | 3.30 | 33.00 |
| Supplier 4 bid | 2.00 | 2.00 | 2.00 | 2.00 | 20.00 |
| Supplier 5 bid | 2.00 | 4.00 | 2.00 | 2.60 | 26.00 |
| Supplier 6 bid | 2.00 | 3.00 | 2.00 | 2.30 | 23.00 |
| Supplier 7 bid | 3.00 | 3.00 | 2.00 | 2.80 | 28.00 |
| Supplier 8 bid | 3.00 | 4.00 | 2.00 | 3.10 | 31.00 |
| Supplier 9 bid | 2.00 | 3.00 | 3.00 | 2.50 | 25.00 |
| Supplier 10 bid | 3.00 | 4.00 | 1.00 | 2.90 | 29.00 |
| Supplier 11 bid | 3.00 | 2.00 | 3.00 | 2.70 | 27.00 |

TABLE 19—COMPOSITE BIDS BY SUPPLIER—Continued

After computing composite bids for each supplier, a pivotal bid is established for each product category in each CBA. In accordance with § 414.402, pivotal bid means the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for items in that category. As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services

is projected using Medicare claims data for allowed services during the previous two years, trended forward to the contract period. Table 20 shows the pivotal bid is the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries for items in a product category. In Table 20, the projected demand is 1,800 units, therefore the composite bid for supplier 7 represents the pivotal bid, since the cumulative

capacity of 1,845 would exceed the projected demand of 1,800. As a result of the determination of the pivotal bid, suppliers 1, 4, 6, 9, 5, 11 and 7 are selected as winning suppliers for the product category in the CBA. However, suppliers 10, 8, 3, and 2 are not selected as winning suppliers for the product category in the CBA and are eliminated from the competition.

TABLE 20—DETERMINING THE PIVOTAL BID FOR PRODUCT CATEGORY POINT WHERE BENEFICIARY DEMAND (1,800) IS MET BY SUPPLIER CAPACITY

| Supplier No. ¹ | Composite bid | Supplier capacity | Cumulative capacity | Result |
|---------------------------|---------------|-------------------|---------------------|--------------|
| 1 | \$1.90 | 250 | 250 | Winning bid. |
| 4 | 2.00 | 300 | 550 | Winning bid. |
| 6 | 2.30 | 0 | 550 | Winning bid. |
| 9 | 2.50 | 300 | 850 | Winning bid. |
| 5 | 2.60 | 360 | 1,210 | Winning bid. |
| 11 | 2.70 | 275 | 1,485 | Winning bid. |
| 7 | 2.80 | 360 | 1,845 | Pivotal bid. |
| 10 | 2.90 | 200 | 2,045 | Losing bid. |
| 8 | 3.10 | 300 | 2,345 | Losing bid. |
| 3 | 3.30 | 200 | 2,545 | Losing bid. |
| 2 | 3.60 | 25 | 2,570 | Losing bid. |

¹ By ascending composite bid.

C. Current Method for Establishing SPAs

For competitively bid items and services furnished in a CBA, the SPAs replace the Medicare allowed amounts established using the lower of the supplier's actual charge or the payment amount recognized under sections 1834(a)(2) through (7), 1834(h), and 1842(s) of the Act. We discussed various options for determining the SPA for individual items under the DMEPOS CBP during the notice and comment rulemaking conducted in 2006 and 2007 (71 FR 25653 and 72 FR 17992, respectively), including using the

minimum winning bid, using the highest winning bid, using the median of winning bids, and using an average adjusted price methodology similar to the methodology used in competitive bidding demonstrations mandated by section 4319 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33). A detailed discussion of the various options considered for determining the SPA for individual items under the DMEPOS CBP can be found in the 2007 DMEPOS final rule (72 FR 17992, 18044 through 18047). Through rulemaking, we finalized using the median of bids submitted for each item by winning

bidders in each CBA as the methodology for establishing the SPA for each item in each CBA.

Under the current methodology for establishing SPAs at § 414.416, for individual items within each product category in each CBA, the median of the winning bids for each item is used to establish the SPA for that item in each CBA. The individual items are identified by the appropriate HCPCS codes. In cases where there is an even number of winning bids for an item, the SPA is equal to the average (mean) of the two bid prices in the middle of the array. Table 21 illustrates this method.

| TARIF 21- | -Median of | THE WINNING | RIDS I | METHODOLOGY |
|-----------|------------|-------------|--------|-------------|
| | | | | |

| Item | Α | В | С | Composite bid |
|------------------------------|--------|--------|--------|---------------|
| Supplier 1 bid | \$1.00 | \$4.00 | \$1.00 | \$1.90 |
| Supplier 4 bid | 2.00 | 2.00 | 2.00 | 2.00 |
| Supplier 6 bid | 2.00 | 3.00 | 2.00 | 2.30 |
| Supplier 9 bid | 2.00 | 3.00 | 3.00 | 2.50 |
| Supplier 5 bid | 2.00 | 4.00 | 2.00 | 2.60 |
| Supplier 11 bid | 3.00 | 2.00 | 3.00 | 2.70 |
| Supplier 7 bid (pivotal bid) | 3.00 | 3.00 | 2.00 | 2.80 |
| Median/SPA | 2.00 | 3.00 | 2.00 | |

We stated in 2007 that we believed that setting the SPA based on the median of the winning bids satisfies the statutory requirement that SPAs are to be based on bids submitted and accepted. We believed that this methodology results in a single payment for an item under a competitive bidding program that is representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item. The median is also not influenced by outliers at the extremes of the data set. This methodology also has the advantage of being easily understood by bidding suppliers.

We received several comments on determining the SPA as a part of the rulemaking process for the 2007 DMEPOS final rule (72 FR 18046). Most of the commenters disagreed with the median bid methodology and supported the average adjusted price methodology. Numerous commenters suggested that CMS use the average adjusted price methodology that was used during the BBA demonstrations because suppliers were paid at least as much as they bid in aggregate, and commenters believed that the average adjusted price methodology would provide sufficient protections to encourage small suppliers

to bid. Several commenters indicated that if contract suppliers with bids above the median amount cannot furnish items and services at payment amounts set below their bid amounts, demand for items and services might not be met and access to necessary items and services would be impaired. The commenters raised concerns that all bids would be equal in terms of establishing the median amount, and bids from small suppliers that only furnish a small percentage of the overall demand for items and services would have the same weight as bids from suppliers that would be responsible for furnishing the majority of the items and services. Other commenters suggested that the use of the median bid favors large chain suppliers that deliver a large volume of items and services.

The average adjusted price methodology for establishing the SPA for an item was discussed in the 2007 DMEPOS final rule (72 FR 18045). This methodology involved using the average of the winning bids adjusted up to the point where the adjusted bids for each supplier in the winning range equals the level of the pivotal bid. This type of methodology was used during the competitive bidding demonstrations

mandated by section 4319 of the BBA. The first step of the methodology is to calculate the average of the winning bids per individual item. The second step is to calculate the average of the composite bids for the winning suppliers by taking the sum of the composite bids for all winning suppliers in the applicable CBA and dividing by the number of winning suppliers. The third step determines an adjustment factor by dividing the composite bid for the pivotal bidder by the average composite bid, and using this factor to increase every winner's overall bids for a product category to the level of the pivotal bidder's composite bid. The fourth step multiplies the average of the winning bids per item by the adjustment factor to adjust all bids up to the point of the pivotal bid, so that all winners would be paid for furnishing all items and services in the product category (the composite payment) equal to the composite bid of the pivotal bidder. This amount would become the SPA for the individual item. This is the price that all contract suppliers within a CBA would be paid for that product as illustrated in Table 22.

TABLE 22—AVERAGE ADJUSTED PRICE METHODOLOGY

| | I | | | I | |
|--------------------------------|--------|--------|--------|-----------------------------|-------------------------------|
| Item | А | В | С | Average composite bid | Composite bid ¹ |
| Item weight | 0.5 | 0.3 | 0.2 | | |
| Supplier 1 bid | \$1.00 | \$4.00 | \$1.00 | | \$1.90 |
| Supplier 4 bid | 2.00 | 2.00 | 2.00 | | 2.00 |
| Supplier 6 bid | 2.00 | 3.00 | 2.00 | | 2.30 |
| Supplier 9 bid | 2.00 | 3.00 | 3.00 | | 2.50 |
| Supplier 5 bid | 2.00 | 4.00 | 2.00 | | 2.60 |
| Supplier 11 bid | 3.00 | 2.00 | 3.00 | | 2.70 |
| Supplier 7 bid (pivotal bid) | 3.00 | 3.00 | 2.00 | | 2.80 |
| Average of winning bids | 2.14 | 3.00 | 2.14 | \$2.40 | |
| Adjustment factor ² | 1.167 | 1.167 | 1.167 | | |
| Average adjusted price/SPA | 2.50 | 3.50 | 2.50 | | |

¹ Sum of item bids multiplied by item weights.

²The adjustment factor is equal to the pivotal bid (\$2.80 in this example) divided by the average composite bid (\$2.40 in this example). The SPA is established by multiplying the average of the winning bids for each item by the adjustment factor.

This methodology, similar to the one used under the BBA demonstrations from October 1, 1999 through December 31, 2002, results in payment to all winning suppliers at the pivotal bid (or highest winning composite bid) level. Under the BBA demonstrations, the adjustment factor varied by supplier and was based on the pivotal composite bid divided by the individual, winning supplier's composite bid, and the average of the prices was calculated after the bids were adjusted rather than before they were adjusted. Both versions of the average adjusted price methodology result in pricing at the pivotal bid level. For example, in Table 22 the methodology used under the BBA demonstrations would have resulted in SPAs of \$2.46, \$3.58, and \$2.48 for items A, B, and C, respectively. However, when factoring in the expected percentage of total services made up by each item in the product category (item weight), both versions of the average adjusted price methodology result in payment at the pivotal bid level:

Table 22: (0.5 * \$2.50) + (0.3 * \$3.50) + (0.2 * \$2.50) = \$2.80

BBA demonstrations: (0.5 * \$2.46) + (0.3 * \$3.58) + (0.2 * \$2.48) = \$2.80

Using either version, the overall payment for the product category equals or exceeds the individual composite bids of \$1.90, \$2.00, \$2.30, \$2.50, \$2.60, \$2.70 and \$2.80. We chose not to propose this approach because we believed that this approach is not reflective of all of the winning bids accepted. In addition, we stated that we were concerned that this methodology may be confusing and overly complicated (72 FR 18046).

Two additional methodologies for determining the SPA for individual items under the DMEPOS CBP include the minimum bid methodology (\$1.00, \$2.00, and \$1.00 in the example above) and the maximum bid methodology (\$3.00, \$4.00, and \$3.00 in the example above). More detailed explanations of these methods can be found in the 2007 DMEPOS final rule (72 FR 17992, pages 18044 through 18047). We did not support either methodology because they only reflect the bid of a single supplier and may be an outlier in the overall bid for the item. A methodology that uses a straight mean is most affected by outliers, since all values in a sample are given the same weight when calculating mean. A value that is far removed from the mean is going to likely skew results.

D. Provisions of the Proposed Rule

We believe that two proposed reforms to the DMEPOS CBP would simplify the program, eliminate the possibility for price inversions, and ensure the long term sustainability of the program.

1. Lead Item Pricing for all Product Categories Under the DMEPOS CBP

In the 2016 ESRD PPS final rule (81 FR 77945), we established alterative rules for submitting bids and determining SPAs for certain groupings of similar items with different features under the DMEPOS CBP. As discussed in the rule, price inversions result under the CBP when different item weights are assigned to similar items with different features within the product category. To prevent this from occurring under future competitions, we established an alternative "lead item" bidding method for submitting bids and determining single payment amounts for certain groupings of similar items (for example, walkers) with different features (wheels, folding, etc.) under the DMEPOS CBP. Under this alternative bidding method, one item in the grouping of similar items would be the lead item for the grouping for bidding purposes. The item in the grouping with the highest total national allowed services (paid units of service) during a specified base period would be considered the lead item of the grouping. CMS established a method for calculating SPAs for items within each grouping of similar items based on the SPAs for lead items within each grouping of similar items (81 FR 42878). Under § 414.416(b)(3), in the case of competitions where bids are submitted for an item that is a combination of codes for similar items within a product category as identified under § 414.412(d)(2), the single payment amount for each code within the combination of codes is equal to the single payment amount for the lead item or code with the highest total nationwide allowed services multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia (DC), Puerto Rico, and the U.S. Virgin Islands) for the code to the average of the 2015 fee schedule amounts for all areas for the lead item. Beginning in 2016, the fee schedule amounts used to pay claims in non-CBAs were adjusted based on information from the CBP. Thus, the 2015 fee schedule amounts were the last fee schedule amounts that were not adjusted based on SPAs for low weight items (for example, hospital beds without side rails) that in some cases were higher than the SPAs for other similar items in the same product

category with more features (for example, hospital beds with side rails). The relative difference in the cost of the items (for example, hospital beds with side rails cost more than hospital beds without side rails) is reflected in the unadjusted fee schedule amounts in that the unadjusted fee schedule amounts for hospital beds with side rails are higher than the fee schedule amounts for hospital beds without side rails, and not in the adjusted fee schedule amounts, where the adjusted fee schedule amounts for hospital beds with side rails are not higher than the fee schedule amounts for hospital beds without side rails. For this reason, we use the unadjusted fee schedule amounts for 2015 to determine the relative difference in the cost of different items (for example, hospital beds with side rails compared to hospital beds without side rails).

Under the CBP, in all rounds since 2011, we found price inversions for groupings of similar items within the following categories: Standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, TENS devices, support surface mattresses and overlays and seat lift mechanisms. We consider the price of an item inverted when a more complicated item is cheaper than a simple version. For instance, when a walker without wheels costs more than a walker with wheels. The detailed method, examples, and responses to public comments regarding lead item bidding were explained in the 2016 ESRD PPS final rule (81 FR77945 through 77949). We are now proposing to establish a similar lead item pricing methodology for all items and all product categories under the DMEPOS CBP. We propose that the methodology would now apply to all items in the product category rather than groupings of items within a product category. We also propose that the lead item would be identified based on total national allowed charges rather than total national allowed services. We believe that lead item pricing would address all price inversions we have already identified as well as potential future price inversions for other items. The lead item pricing methodology proposed in this rule is therefore similar to, but different than the lead item bidding methodology we finalized in previous rulemaking. This would not be an alternative bidding method, but would replace the current bidding method, where bids are submitted for each item in the product category, for all items. Since the bid for the lead item would be used to establish the SPAs for both the lead item and all other items in the

product category, we are referring to this proposed policy as "lead item pricing" rather than "lead item bidding." We are proposing to implement lead item pricing and change the methodology for establishing SPAs under the CBP for a number of reasons.

We believe lead item pricing would greatly reduce the complexity of the bidding process and the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. For some product categories, there are hundreds of items, and many suppliers submit bids for multiple product categories and in multiple CBAs. The more bids a supplier has to submit, the more time it takes to complete the bidding process and the greater the risk for keying errors, which have disqualified bidders in the past, reducing the level of competition and opportunity for savings under the program. Lead item pricing would also eliminate the need for item weights and calculation of composite bids based on item weights. This would greatly eliminate the burden for suppliers since they would no longer have to submit bids for each individual item in a product category.

Several issues related to this lead item pricing proposal warrant discussion. First, lead item pricing would apply to all items in each product category, including all codes for base equipment (for example, power wheelchairs) and all codes for accessories for base equipment (for example, wheelchair batteries). Bids for the lead item (for example, one of the power wheelchair codes), would therefore be used to establish the SPA for the code for the lead item, other codes for power wheelchairs other than the lead item, and codes for accessories used with the base equipment (in this example, various types of power wheelchairs). Examples of how this pricing method would work are in section V.D.2 of this proposed rule.

Second, it is likely that some of the larger, conglomerate product categories established to promote "one stop shopping" for beneficiaries and referral agents would need to be split into multiple product categories so that lead item pricing is not implemented for categories that include different types of base equipment. Such categories include general home equipment (hospital beds, support surfaces, commode chairs, patient lifts, and seat lifts), respiratory equipment (oxygen and oxygen equipment, continuous positive airway pressure devices, and respiratory assist devices), and standard mobility equipment (walkers, standard manual wheelchairs, standard power

wheelchairs, and scooters). We believe that it would be overly complex and confusing to establish prices for one type of equipment (for example, power wheelchairs) based on bids submitted for another type of equipment (for example, walkers). We believe it would be more straightforward for suppliers to submit a lead item bid for one code for one type of base equipment (for example, group 2, captains chair power wheelchair, which is a lead item because it has the highest allowed charges) that would be used to establish payment amounts for all similar types of the base equipment that is, power wheelchairs (for example, groups 1 and 2, captains chair and sling seat versions, and equipment accommodating various patient weight capacities) and accessories used with the various power wheelchairs (for example, batteries, arm pads, and tires).

Third, as part of the proposal to move to lead item pricing, we are proposing to establish a new definition under § 414.402 for "lead item," and we are proposing to revise the current definitions for "bid" and "composite bid" under § 414.402. We propose to revise the definition of "bid" to include the words "or items" after the word "item". The definition of "bid" would read as follows "Bid means an offer to furnish an item or items for a particular price and time period that includes. where appropriate, any services that are directly related to the furnishing of the item or items." We are proposing this change because under lead item pricing, the bid for a lead item includes the supplier's bid for furnishing all of the items in the product category and not just the lead item.

We propose to revise the definition of "composite bid". The definition would read as follows "Composite bid means the bid submitted by the supplier for the lead item in the product category."

Currently, the supplier's bid amounts for multiple items in the product category are weighted and summed to generate the supplier's composite bid for that product category. Under lead item pricing, the supplier's bid amount for the lead item is the composite bid. In addition, the bids for the lead items would be used to determine the SPAs for the rest of the items in the product category. We would educate suppliers regarding how pricing for all of the items in the product category would be established based on the bids submitted for the lead item, and that they should consider their costs for furnishing the various items in the product category when submitting their bid for the lead item.

As indicated in section V.A of this proposed rule, section 1847(a)(1)(G) of the Act and our regulations require that bidding suppliers obtain bid surety bonds when participating in future competitions under the CBP. If the supplier is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding suppliers included in the calculation of the SPAs for the product category/CBA combination, the supplier must accept the contract offered or the supplier's bid surety bond for the applicable CBA will be forfeited. Because we are proposing a change to the definition of composite bid (the composite bid would be defined as the supplier's bid for the lead item in the product category), we note that the supplier's bid for the lead item would also be treated as the "composite bid" for the purpose of implementing the statutory and regulatory bid surety bond requirement. Under the lead item pricing method, suppliers would forfeit their bid surety bond for a product category in a CBA if their composite bid (their bid for the lead item) is at or below the median composite bid rate for all bidding suppliers included in the calculation of SPAs for the product category and CBA and they do not accept a contract offer for the product category and CBA. In other words, the median of the winning bids for the lead item in the product category would be calculated and used to implement the bid surety bond requirement at section 1847(a)(1)(H)(i) of the Act and § 414.412(h).

We are proposing to add the definition for "lead item" under § 414.402. The definition of "lead item" would read as follows "Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. Total nationwide Medicare allowed charges means the total sum of charges allowed for an item furnished in all states, territories, and D.C. where Medicare beneficiaries reside and can receive covered DMEPOS items and services."

Currently under § 414.412(d)(2) the "lead item" in the product category is described as "the code with the highest total nationwide allowed services for calendar year 2012," and "total nationwide allowed services" is defined in § 414.402 as meaning the total number of services allowed for an item furnished in all states, territories, and DC where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We are proposing to delete

the lead item bidding provision that currently appears in § 414.412(d)(2) and replace it with the proposed lead item pricing provision. We are proposing to change these descriptions and definitions as explained by replacing this language in § 414.412(d)(2) with a new definition of lead item in § 414.402. We believe that using allowed charges rather than allowed services is a better way to identify the lead item in a product category for the purpose of implementing lead item pricing because the item with the highest allowed charges is the item that generates the most revenue for the suppliers of the items in the product category. The item with the most allowed services is not always the item that generates the most revenue for the supplier. For example, there are far more allowed services for NPWT dressings than NPWT pump rentals, but the revenue generated by the pump rentals is more than double the revenue generated by the dressings. Therefore, the item with the most allowed charges in the product category (the NPWT pump rentals) generates more revenue for the suppliers than the item with the most allowed services in the product category (the NPWT dressings). We note that in most cases the item with the most allowed charges would also be the item with the most allowed services, but in cases where this is not true, we believe that the lead item should be the one that generates the most revenue for suppliers as opposed to the one that has the higher number of allowed services.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under the CBP unless the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. In order to implement this requirement for assurance of savings under the CBP, we propose to revise § 414.412(b)(2) to require that the supplier's bid for each lead item and product category in a CBA cannot exceed the fee schedule amount that would otherwise apply to the lead item without any adjustments based on information from the CBP.

Finally, we propose to amend the conditions for awarding contracts under the CBP in § 414.414(e) related to evaluation of bids under the CBP. Currently, this section indicates that CMS evaluates bids submitted for items within a product category, and that expected beneficiary demand in a CBA is calculated for items in the product category. We are proposing to change this section to indicate that CMS evaluates composite bids submitted for the lead item within a product category, and that expected beneficiary demand

in a CBA is calculated for the lead item in the product category. We are proposing that under the lead item pricing methodology, CMS would calculate expected beneficiary demand and total supplier capacity based on the lead item in the product category when evaluating bids. Currently, beneficiary demand for items in a product category and supplier capacity for furnishing items in the product category are calculated based on historic utilization of the items making up at least 80 percent of the total expenditures for the product category as a whole. The demand for these items is trended forward to the contract period by the projected growth in beneficiary population in the CBA and utilization of the items in the product category. The pivotal bid is where total supplier capacity for furnishing the items within a product category meets projected beneficiary demand for the items. Projected demand for items within a product category and supplier capacity for meeting the projected demand for items within a product category are calculated by adding the projected demand and supplier capacity for those items in the product category that make up 80 percent of the total expenditures for the product category. It is assumed that the suppliers with the capacity to furnish the items making up 80 percent of the total expenditures for the product category would also have the capacity to furnish the remaining items in the product category as well. This has proven to be true. Under lead item pricing, we are proposing that projected demand and supplier capacity would only be calculated for the lead item for the purpose of determining or establishing the pivotal bid. In other words, the winning range of suppliers would be set based on where the cumulative capacity of suppliers for furnishing the lead item equals or exceeds the projected beneficiary demand for the lead item. It is assumed that the suppliers with the capacity to furnish the lead item in the product category would also have the capacity to furnish the remaining items in the product category as well. We believe this change would have a minimal impact on the number of contracts awarded under the program, with the exception of CPAP devices and accessories. For this category of items, the CPAP device would be the lead item, but there are also several codes for accessories (masks, tubing, etc.) where total allowed charges are close to the allowed charge total for the CPAP device itself. Establishing projected demand and supplier capacity based on

the CPAP device alone could result in a drop in the number of winning suppliers; however, we believe that suppliers that have the capacity to meet projected beneficiary demand for rental of the CPAP device would also have the capacity to furnish the accessories used with the devices they are furnishing. In addition, the 20 percent cap on supplier capacity would still be in effect, which limits the capacity of suppliers, including large, national chain suppliers, to 20 percent of projected demand, even if these suppliers could meet far more than 20 percent of beneficiary demand for CPAP devices and accessories.

In summary, we propose to amend §§ 414.402, 414.412, and § 414.414 to change the definitions, the methodology for the calculation of SPAs, and the evaluation of bids under the CBP to reflect and establish the lead item pricing methodology.

2. Calculation of Single Payment Amounts (SPAs) Using Maximum Winning Bids for Lead Items

We propose to revise § 414.416 to change the methodology for calculating SPAs under the CBP. The SPA for the lead item in each product category and CBA would be based on the maximum or highest amount bid for the item by suppliers in the winning range as illustrated in Table 23. The SPAs for all other items in the product category would be based on a percentage of the maximum winning bid for the lead item. Specifically, the SPA for a non-lead item in the product category would be equal to the SPA for the lead item multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, DC, Puerto Rico, and the U.S. Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item. Thus, the SPAs for a non-lead item would be based on the relative difference in the fee schedule amounts for the lead and non-lead item before the fee schedule amounts were adjusted based on information from the CBP. For example, if the average 2015 fee schedule amount for a non-lead item such as a wheelchair battery is \$107.25, and the average 2015 fee schedule amount for the lead item (Group 2, captains chair power wheelchair) is \$578.51, the ratio for these two items would be computed by dividing \$107.25 by \$578.51 to get 0.18539. Multiplying \$578.51 by 0.18539 then generates the amount of \$107.25. Under the lead item pricing methodology, if the maximum winning bid for the lead item in this example (Group 2, captains chair power wheelchair) is used to compute an SPA

of \$433.88 for this lead item, then the SPA for the non-lead item in this example (wheelchair battery) would be computed by multiplying \$433.88 by 0.18539 to generate an SPA of \$80.44 for the non-lead item (wheelchair battery).

We believe that establishing the SPA for the lead item based on the maximum winning bid rather than the median of winning bids could also further simplify the bidding process and better ensure the long term sustainability of the CBP. The maximum winning bid is the bid for the lead item submitted by the supplier with the pivotal bid, defined in § 414.402 as the lowest composite bid based on bids submitted by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category. Under the proposed revised definition of composite bid, each supplier's bid for the lead item would be their composite bid. In no case would a supplier in the winning range be paid an amount for the lead item in a product category that is less than its bid amount for the lead item, or its composite bid, for the product category as a whole. We believe that this is the best way to ensure that the supplier can furnish the quantity of items and services it indicates it can furnish with its bid. As an alternative to using median bids to establish SPAs, we are proposing to use the maximum winning bid for the lead item in a product category to establish the SPAs for the rest of the items in the product category in order to ensure long term sustainability of the DMEPOS CBP. We believe that lead item pricing based on the maximum winning bid for the lead item is the best way to ensure that the supplier can furnish the quantity of items and services it indicates it can furnish with its bid because all suppliers in the winning range would be paid at least what they bid for the lead item or more. Currently, suppliers are paid based on the median of the winning bids for each item, which results in many suppliers being paid less than the amount they bid for an item, which could potentially lead to beneficiary access problems for these items if the SPA based on the median of the winning bids is not sufficient to cover the supplier's costs for furnishing the quantity of items they indicated that they could furnish with their bid. Currently under the CBP, certain suppliers can be offered contracts after the initial contract awards are made if necessary to ensure access to items and services. These suppliers are suppliers that had composite bids above the pivotal bid, so their bids are even

further removed from the median bid levels than the suppliers initially awarded contracts. As median bid levels continue to decline over time, we believe that it is possible that many of the suppliers with bids above the median would not be willing or able to accept contracts for items and services with SPAs that were set using the median of winning bids. We believe this could potentially jeopardize the program. If there are not enough suppliers willing to accept contract offers and meet beneficiary demand, then this would result in no contracts or payments at SPA levels set too low to ensure access. We believe this possible scenario could be avoided by changing the way that the SPAs are calculated, and using the proposed maximum winning bid for the lead item in a product category to establish the SPAs for all items in the product category, rather than using the median of winning bids to establish the SPA for each item in a product category. Also, by applying lead item pricing to all items, it would eliminate price inversions associated with suppliers bidding high for low weight items, since items weights and bids for low weight items would no longer be used to establish SPAs for items under the CBP.

Bids from small suppliers that are only awarded contracts in order to help meet the small supplier target would not be used to determine the maximum winning bid because these contracts are awarded after the SPAs are established. Under $\S 414.414(g)(1)(i)$, we established a 30 percent target for small supplier participation in the CBP; thereby ensuring efforts are made to award at least 30 percent of contracts to small suppliers. If less than 30 percent of the suppliers in the winning range (suppliers at or below the pivotal bid) are not small suppliers, additional contracts are offered to small suppliers who bid above the pivotal bid in order to attempt to meet this 30 percent small supplier target. However, the bids above the pivotal bid have not been used to calculate the SPA in past competitions, and will not be used to calculate the SPA going forward. If small suppliers who are offered contracts do not accept them, we may not meet the small supplier target, but this refusal of the contract offers would not result in an access problem. The small supplier target is just a target for enhancing participation of small suppliers in the CBP and is not a threshold that must be met in order to meet demand for items and services. Currently, small suppliers not in the winning range who are only offered contracts in an attempt to meet

this target must accept payment at the median of the winning bids for each item, which in most cases are amounts that are below what they bid for the item. While SPAs based on the proposed maximum winning bids would still be below what these suppliers bid, they are generally going to be closer to the amounts they bid than the SPAs based on the median of the winning bids.

Likewise, bids from other suppliers awarded contracts after the SPAs are established are not currently used to determine the SPAs and would not be used to determine the maximum winning bid. Currently, in very limited cases, suppliers are offered and awarded contracts after the SPAs are established and contract offers are made because of errors that were made in the bid evaluation process. Also, additional contracts can be offered at any point during the contract period if necessary to ensure beneficiary access to items and services. The SPAs are not recalculated in these situations because it would be very disruptive and logistically challenging to change the SPAs and repeat the contracting process each time an additional contract is offered and accepted. The process for completing all of the steps necessary for CMS to implement a competition under the CBP from the time the competition is announced and suppliers are registered to bid in DBids (the online bidding system) to the time the contract period begins already takes approximately 2 years.

Under the current methodology for establishing SPAs, for individual items within each product category in each CBA, the median of the winning bids for each item is used to establish the SPA for that item in each CBA, as illustrated in Table 21. The proposed methodology of using the maximum winning bids to establish SPAs is illustrated in Table 23.

TABLE 23—PROPOSED MAXIMUM WINNING BIDS METHODOLOGY

| Supplier bids | Bid amounts for the lead item |
|------------------------------|-------------------------------------|
| Supplier 1 bid | \$1.00 |
| Supplier 4 bid | 2.00 |
| Supplier 6 bid | 2.00 |
| Supplier 9 bid | 2.00 |
| Supplier 5 bid | 2.00 |
| Supplier 11 bid | 3.00 |
| Supplier 7 bid (pivotal bid) | 3.00 |
| Maximum bid/SPA | 3.00 |

As shown in this Table 23, the maximum winning bid, the pivotal bid, and the SPA are all equal.

We stated in the 2007 DMEPOS final rule that we believed that setting the SPA based on the maximum of the winning bids is not representative of all bids submitted. However, we now believe that using the maximum winning bid amount for the lead item to establish the SPAs and paying most contract suppliers more than they bid helps to ensure access and long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Using the maximum winning bid for the

lead item to establish SPAs addresses criticism from stakeholders that the use of median bids to establish SPAs results in CMS paying approximately half of the winning suppliers below what they bid for the item. Using the maximum winning bid is also strongly supported by the supplier community, as expressed in comments described in the preamble to the 2007 DMEPOS final rule (72 FR 18046). Under the CBP, suppliers have consistently accepted contract offers 92 percent of the time, even though the median bid levels have

trended lower with each successive round of competitions. However, if bid levels continue to trend downward, we believe this could ultimately result in many suppliers rejecting contract offers, to the point where there may not be enough suppliers accepting contracts to meet demand for items and services. Table 24 shows the average SPAs for seven high volume items that have been included in all rounds of bidding and how they have changed with each successive recompete of the contracts.

TABLE 24—CHANGE IN AVERAGE SPAS OVER ROUNDS OF BIDDING

| Round | Year | SPA | Year | SPA | Change % |
|-------|------|-----------------------|--------------------------|------------|-------------|
| | E13 | 90—Oxygen Concentrato | or/Oxygen and Oxygen I | Equipment | |
| 1 | 2011 | \$116.16 | 2014 | \$95.74 | -18 |
| 1 | 2014 | 95.74 | 2017 | 77.97 | -19 |
| 2 | 2013 | 93.07 | 2016 | 76.84 | – 17 |
| | | E060 | 01—CPAP | | |
| 1 | 2011 | \$582.31 | 2014 | \$518.58 | -11 |
| 1 | 2014 | 518.58 | 2017 | 426.76 | -18 |
| 2 | 2013 | 466.02 | 2016 | 397.60 | -15 |
| | | K0823—Group 2 Sta | andard Power Wheelcha | ir | |
| 1 | 2011 | \$2,554.22 | 2014 | \$2,189.28 | -14 |
| 1 | 2014 | 2,189.28 | 2017 | 1,770.17 | -19 |
| 2 | 2013 | 1,889.48 | 2016 | 1,785.41 | -6 |
| | | B4035—Daily Supplies | for Enteral Nutrition by | Pump | |
| 1 | 2011 | \$7.50 | 2014 | \$5.79 | -23 |
| 1 | 2014 | 5.79 | 2017 | 5.22 | -10 |
| 2 | 2013 | 5.98 | 2016 | 5.25 | -12 |
| | | E0143—Foldi | ng Wheeled Walker | | |
| 1 | 2011 | \$66.13 | 2014 | \$58.79 | -11 |
| 1 | 2014 | 58.79 | 2017 | 47.89 | -19 |
| 2 | 2013 | 53.22 | 2016 | 45.93 | -14 |
| | | E0260—Semi-E | Electric Hospital Bed | | |
| 1 | 2011 | \$803.45 | 2014 | \$738.59 | -8 |
| 1 | 2014 | 738.59 | 2017 | 615.22 | - 17 |
| 2 | 2013 | 703.14 | 2016 | 591.30 | - 16 |
| | | E0277—Powered N | Mattress Support Surface | e | |
| 1 | 2011 | \$3,197.50 | 2014 | \$2,855.09 | -11 |
| 1 | 2014 | 2,855.09 | 2017 | 2,257.05 | -21 |
| 2 | 2013 | 2,351.77 | 2016 | 1,748.70 | -26 |
| | 2010 | 2,001.77 | 2010 | 1,7 40.70 | |

If the median bids continue on this downward trend, suppliers with bids above the median bid may not be able to continue to furnish items and services at the SPAs established based on the median of winning bids, and this could cause problems with securing enough contract suppliers to meet demand and could cause non-viable programs in certain areas for certain product categories. We believe

establishing SPAs based on the maximum winning bid for the lead item would help prevent such a scenario from unfolding and would enhance the long term sustainability of the DMEPOS CBP. We believe current tools used to address potential access or demand issues in CBAs, such as awarding additional contracts, may become insufficient if suppliers in the upper half of the winning range (those that bid

at or below the pivotal bid, but above the median) stop accepting contract offers because the SPAs over time have decreased to the point where they are unacceptable to these suppliers.

We believe that the maximum winning bid methodology would enable long term sustainability of the CBP but has some risks. This methodology could skew the data set of bids if there is an outlier. For example, in Table 23, if one

supplier bids \$20 and the majority of suppliers bid between \$1 and \$3, this would cause the entire item price to be inaccurately skewed in one direction and would increase the cost of the item significantly. Although there are some hindrances in replacing the median bid amount methodology with the maximum winning bid methodology for determining the SPA, such as the risk of skewed bids and the risk of paying suppliers more than necessary to meet beneficiary demand, we believe that the pros of reducing burden and enhancing access to items and services and sustainability of the competitive bidding program outweigh these cons. We solicit comments on ways to minimize these

With regard to the fiscal impact of the proposal to use lead item pricing and maximum winning bids to establish SPAs, we believe that use of maximum winning bids to establish SPAs for lead items would increase payment amounts and expenditures for these lead items, but would also decrease payment amounts and expenditures for many of the non-lead items, which should offset the cost of the payments for the lead items. For example, the monthly rental SPA for the NPWT pump (E2402) for the Virginia Beach, Virginia CBA is \$654.89 (60 percent less than the fee schedule amount of \$1,642.09) and the purchase SPA for the NPWT dressing (A6550) is \$25.39 (only 3 percent less than the fee schedule amount of \$26.25). In 2017, approximately \$356,257 was spent on the pump in this CBA while approximately \$154,752 was spent on the dressings. Under lead item pricing, code E2402 would be the lead item, and the maximum winning bid for this item under the Round 2 Recompete (2016) was \$839.00 per month (49 percent less than the fee schedule amount of \$1,642.09). Had this amount been paid in 2017 in the Virginia Beach CBA, it would have increased expenditures for NPWT pump (E2402) by approximately \$100,159 from \$356,257 to approximately \$456,416. However, using lead item pricing, the price for the dressing would have decreased from \$25.39 to \$13.41 (49 percent less than the fee schedule amount of \$26.25), which would have decreased expenditures for code A6550 by approximately \$73,018 from \$154,752 to approximately \$81,734. The net increase in expenditures in this example would have been approximately \$27,141 (\$100,159 - \$73,018).

In summary, we propose to amend the SPA determination methodology in § 414.416 to change the methodology from one that uses the median of winning bids for each item to establish

the SPAs for each item to one that uses the maximum winning bid for the lead item to set the SPA for the lead item and the rest of the items within the product category ("non-lead items"). The SPAs for each non-lead item would be based on the relative difference in the fee schedule amounts for the non-lead item and the lead item in 2015, before the fee schedule amounts were adjusted based on information from the CBP.

Finally, we are interested in obtaining feedback from the public on whether or not certain large CBAs should be split into smaller size CBAs to create more manageable service areas for suppliers, as has been done for the New York, Los Angeles, and Chicago CBAs. We are soliciting feedback that we can consider in potentially adjusting the size and boundaries of CBAs for future competitions. There are currently nine CBAs with more than 7,000 square miles, and three of these CBAs are areas with more than 9,000 square miles. The largest CBA is the Phoenix-Mesa-Scottsdale, Arizona CBA with approximately 12,000 square miles. This CBA is comprised of the two counties, Maricopa (approximately 8,000 square miles) in the northwest and Pinal (approximately 4,000 square miles) in the southeast. One option for reducing the size of this CBA would be to split the CBA in two based on the county borders and then remove some of the large low population density zip code areas from the southwestern portion of the new Maricopa County CBA to reduce the size of this CBA. Interstate highway 10 runs west to east and then south through the northern part of the current CBA (primarily Maricopa County), while interstate highway 8 runs west to east through the southern part of the current CBA (primarily Pinal

The second largest CBA is the Boise City, Idaho CBA, comprised of five counties, approximately 11,800 square miles. Three zip code areas (83604, 83624, and 83650) south of the Snake River and interstate highway 84 in Owyhee County make up almost 65 percent of the area for the CBA (approximately 7,700 square miles), but only 2 percent of the population. Removing these three zip codes from the CBA would reduce the size of the CBA to a little over 4,000 square miles. The average size of the 130 CBAs is approximately 2,900 square miles. The third largest CBA is the Dallas-Fort Worth-Arlington, Texas CBA with approximately 9,100 square miles. The Dallas-Fort Worth-Arlington, Texas MSA and is made up of the two metropolitan divisions of Dallas-Plano-Irving (approximately 5,000 square

miles over eight counties) and Fort Worth-Arlington (approximately 4,000 square miles over seven counties). This CBA could potentially be divided into two new CBAs based on the metropolitan divisions. The other six CBAs with more than 7,000 square miles are Riverside-San Bernardino-Ontario, California (approximately 8,900 square miles), Houston-The Woodlands-Sugar Land, Texas (approximately 8,800 square miles), Bakersfield, California (approximately 8,100 square miles), Salt Lake City, Utah (approximately 7,500 square miles), San Antonio-New Braunfels, Texas (approximately 7,300 square miles), and Atlanta-Sandy Springs-Roswell, Georgia (approximately 7,300 square miles).

We are soliciting feedback on whether certain large CBAs should be subdivided to make the areas more manageable to serve. One result of subdividing the CBAs and creating more CBAs is that suppliers who wish to bid for furnishing items and services in all of the areas that formerly would have been one area would have to incur the cost and effort of obtaining multiple bid surety bonds for the new areas rather than one bid surety bond.

VI. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

A. Background

Section 16008 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114– 255) was enacted on December 13, 2016, and amended section 1834(a)(1)(G) of the Act to require in the case of items and services furnished in non-CBAs on or after January 1, 2019, that in making any adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and (iii), 1834(a)(1)(H)(ii), or 1842(s)(3)(B) of the Act, the Secretary shall: (1) Solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.
- 1. Stakeholder Input Gathered in Accordance With Section 16008 of the Cures Act

Section 16008 of the Cures Act mandates that we solicit and take into

account stakeholder input in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. In order to solicit stakeholder input, we announced that we would be hosting a Medicare Learning Network (MLN) ConnectsTM National Provider Call (MLN Connects Call), which are educational conference calls conducted for the Medicare provider and supplier community that educate and inform participants about new policies and/or changes to the Medicare program. We announced this call through multiple CMS listservs throughout March 2017, in order to get the word out as quickly and directly as possible to our stakeholders. On March 23, 2017, CMS hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using information from the DMEPOS CBP. The national provider call was announced on March 3, 2017, and we requested written comments by April 6, 2017.

We received 125 written comments from stakeholders. More than 330 participants called into our national provider call, with 23 participants providing oral comments during the call. In general, the commenters were mostly suppliers, but also included manufacturers, trade organizations, and healthcare providers such as physical and occupational therapists. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. Stakeholders requested an increase to the adjusted payment amounts for these areas. The written comments generally echoed the oral comments from the call held on March 23, 2017, whereby stakeholders claimed that the adjusted fees are not sufficient to cover the costs of furnishing items and services in non-CBAs and that this is having an impact on access to items and services in these areas.

The oral and written comments are organized into the following categories:

Inadequacy of Adjusted Fee Schedule Amounts: Commenters claim the adjusted fee schedule amounts do not cover the cost of furnishing the items and are not sustainable. Many commenters opposed the current adjusted payment amounts as insufficient to sustain the current cost of doing business. Some commenters stated that current reimbursement levels are below the cost of doing business. Many commenters stated they were billing non-assigned for items, or were considering billing non-assigned in the future.

Travel Distance: Commenters claim the average travel distance and cost for suppliers serving rural areas are greater than the average travel distance and cost for suppliers serving CBAs. Many commenters described farther travel distances in rural areas than in nonrural areas. (For the purpose of implementing the fee schedule adjustment methodologies at § 414.210(g), the term "rural area" is defined at § 414.202 and essentially includes any areas outside an MSA or excluded from a CBA).

Volume of Services: Many commenters asserted that the average volume of services furnished by suppliers, when serving non-CBAs, are lower than the average volume of services furnished by suppliers, when serving CBAs. Many commenters stated that they do not get the same increase in volume that suppliers who obtain competitive bidding contracts get, which does not allow them to have economies of scale and obtain products at lower costs.

Beneficiary Access: Many commenters stated that the adjusted fees have reduced the number of suppliers in the area, and that this has caused or will cause beneficiary access issues. Some commenters claimed that they were the only supplier in the area.

Adverse Beneficiary Health
Outcomes: Commenters stated that
beneficiaries are going without items
and this is causing adverse health
outcomes. Commenters stated that
hospital readmissions and lengths of
stay, falls, and fractures are increasing
as a result of the fee schedule
reductions

Delivery Expenses: A few commenters provided an estimate of how much their delivery expenses cost, their estimated service radius, and the average distance traveled. Several commenters stated that they have reduced the size of their service area due to the level of reimbursement that they are receiving.

Costs in Rural Areas: Many commenters stated rural areas have unique costs, costs that are higher than non-rural areas. Similar to comments received on our CY 2015 ESRD PPS proposed rule (79 FR 40275 through 40315) and discussed in the CY 2015 ESRD PPS final rule (79 FR 66223 through 66265), some commenters stated that a 10 percent payment increase in rural areas is not enough to cover costs in rural areas. One commenter stated that non-contiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Some

commenters stated specific costs, as well as data sources, that CMS should take into account when adjusting fees in non-CBAs. These included the following: Geographic wage index factors, gas, taxes, employee wages and benefits, wear and tear of vehicle, average per capita income, training, delivery, set up, historical Medicare home placement volume, proximity to nearby CBAs, employing a respiratory therapist, electricity charges, freight charges, 24/7 service, documentation requirements, average per patient cost, licensing accreditation, surety bonds, audits, population density, miles and time between points of service, regulatory costs, vehicle insurance, and liability insurance.

Two commenters pointed to the Ambulance Fee Schedule and one commenter pointed to the Bureau of Labor Statistic Consumer Expenditure Survey as evidence that health care costs in rural areas are higher than in urban areas. Another commenter mentioned the Internal Revenue Service Mileage Rate, the minimum wage, AAA Gallon of Gasoline prices, and the price of a loaf of white bread, to highlight how the prices of such items have increased over the years, while reimbursement for DME has not.

Using the Highest Winning Bids for the Adjusted Fee Schedule
Methodology: Five commenters suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs rather than the median of winning bids in CBAs. One commenter suggested that the maximum winning bids should be the starting point for the adjustments and that additional payment should be added on to these amounts to pay for the higher costs of furnishing items and services in non-CBAs.

2. Highest Winning Bids in CBAs Analysis

Section 16008 of the Cures Act mandates that we take into account the highest amount bid by a winning supplier in a CBA in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We considered the highest amounts bid by a winning supplier for a specific item (maximum bid) in the various CBAs in Round 1 2017 and Round 2 Recompete to see if maximum bids varied in different types of areas (that is, low volume versus high volume areas, large versus small delivery service areas, areas with few suppliers versus many suppliers). We analyzed maximum bids for the lead items in each product category (those with the

highest allowed charges) and for other lower volume items. For lower volume items with low item weights, suppliers had less of an incentive to bid low on these items and therefore the maximum bids for many of these items are not significantly below the unadjusted fee schedule amounts.

For the lead items, we focused primarily on items that clearly are delivered locally such as large bulky hospital beds and oxygen equipment (concentrators and tanks) since variations in maximum bid amounts

from CBA to CBA due to differences in travel distances and costs would be most noticeable for these items. There are 130 CBAs in total in Round 1 2017 and Round 2 Recompete varying greatly in size, volume, and number of suppliers. What we found is that there is no pattern indicating that maximum bids are higher for larger areas with lower volume than they are for smaller areas with higher volume.

Table 25 lists the 130 maximum bids for code E0260 (semi-electric hospital bed). We ranked the CBAs/bids from the

largest maximum bid for E0260 to the lowest maximum bid for E0260. The average volume per supplier for each item is also included and ranked from 1 (lowest average volume per supplier) to 130 (highest average volume per supplier). We looked to see if lower average volumes (for example, rankings 1, 2, 3, etc.) corresponded with higher maximum bid amounts. We also looked to see if larger areas (for example, rankings 1, 2, 3, etc.) corresponded with higher maximum bid amounts.

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260 [Semi-Electric Hospital Bed]

| Area name | Size in square miles | Size rank | Maximum winning bid E0260 | Max E0260 bid rank | Average E0260 services per supplier ¹ | Volume rank (low to high) E0260 |
|---|---------------------------------------|-----------|---------------------------------|-----------------------|---|---------------------------------------|
| Salt Lake City UT | 7,473 | 7 | \$1,343.79 | 1 | 37 | 23 |
| Ocala FL | 1,585 | 88 | 1,325.00 | 2 | 33 | 17 |
| Albuquerque NM | 6,287 | 10 | 1,303.00 | 3 | 35 | 19 |
| Charlotte-Concord-Gastonia NC | 3,788 | 37 | 1,276.61 | 4 | 75 | 68 |
| Kansas City MO | 4,572 | 25 | 1,207.50 | 5 | 51 | 36 |
| Seattle-Tacoma-Bellevue WA | 5,872 | 14 | 1,199.00 | 6 | 34 | 18 |
| Wichita KS | 4,149 | 29 | 1,100.00 | 7 | 61 | 53 |
| Knoxville TN | 3,501 | 39 | 1,100.00 | 7 | 49 | 33 |
| Honolulu HI | 601 | 124 | 1,075.00 | 9 | 46 | 30 |
| Portland-Hillsboro-Beaverton OR | 4,399 | 26 | 1,000.00 | 10 | 61 | 52 |
| McAllen-Edinburg-Mission TX | 1,571 | 90 | 950.00 | 11 | 127 | 107 |
| Colorado Springs CO | 2.684 | 52 | 941.00 | 12 | 22 | 3 |
| Nashville-Davidson-Murfreesboro-Frank- | 2,001 | 02 | 011.00 | | | J |
| lin TN | 6,036 | 12 | 940.00 | 13 | 68 | 60 |
| Phoenix-Mesa-Scottsdale AZ | 12,036 | 1 | 924.82 | 14 | 79 | 73 |
| Riverside-San Bernardino-Ontario CA | 8,900 | 4 | 920.00 | 15 | 53 | 37 |
| Bridgeport-Stamford-Norwalk CT | 625 | 122 | 897.23 | 16 | 84 | 77 |
| Orlando-Kissimmee-Sanford FL | 3,478 | 40 | 873.47 | 17 | 67 | 57 |
| Tampa-St. Petersburg-Clearwater FL | 2,513 | 55 | 850.00 | 18 | 85 | 78 |
| Boise City ID | 11,766 | 2 | 850.00 | 18 | 31 | 14 |
| • | , , , , , , , , , , , , , , , , , , , | 94 | 843.92 | 20 | 138 | 110 |
| Hartford-West Hartford-East Hartford CT | 1,515 | 65 | 840.60 | 21 | 109 | 96 |
| Los Angeles County CA | 2,232 | | | | | |
| New Haven-Milford CT | 605 | 123 | 829.62 | 22 | 157 | 117 |
| Boston-Cambridge-Quincy MA | 2,424 | 59 | 828.19 | 23 | 166 | 119 |
| Kansas City-Overland Park-Ottawa KS | 2,829 | 48 | 819.00 | 24 | 36 | 20 |
| Denver-Aurora-Lakewood CO | 3,906 | 34 | 818.11 | 25 | 24 | 6 |
| Chicago-Naperville-Arlington Heights IL | 1,273 | 103 | 818.10 | 26 | 328 | 130 |
| Wilmington DE | 426 | 127 | 817.41 | 27 | 156 | 116 |
| Fresno CA | 5,958 | 13 | 816.78 | 28 | 30 | 12 |
| Worcester MA | 1,511 | 95 | 814.00 | 29 | 57 | 46 |
| Jeffersonville-New Albany IN | 1,709 | 82 | 811.56 | 30 | 95 | 87 |
| Scranton-Wilkes-Barre-Hazleton PA | 1,747 | 81 | 807.35 | 31 | 142 | 112 |
| Greensboro-High Point NC | 1,994 | 73 | 805.31 | 32 | 73 | 65 |
| Indianapolis-Carmel-Anderson IN | 3,994 | 33 | 800.00 | 33 | 120 | 101 |
| Minneapolis-St. Paul-Bloomington MN | 4,731 | 23 | 800.00 | 33 | 94 | 86 |
| El Paso TX | 1,013 | 112 | 800.00 | 33 | 74 | 66 |
| Austin-Round Rock TX | 4,220 | 27 | 800.00 | 33 | 58 | 47 |
| Beaumont-Port Arthur TX | 3,034 | 46 | 800.00 | 33 | 37 | 24 |
| Lakeland-Winter Haven FL | 1,798 | 80 | 798.88 | 38 | 71 | 63 |
| Deltona-Daytona Beach-Ormond Beach | | | | | | |
| FL | 1,586 | 87 | 798.88 | 38 | 45 | 29 |
| Silver Spring-Rockville-Bethesda MD | 1,152 | 105 | 789.00 | 40 | 104 | 93 |
| Augusta-Richmond County GA | 1,909 | 76 | 787.00 | 41 | 101 | 90 |
| Atlanta-Sandy Springs-Roswell GA | 7,275 | 9 | 787.00 | 41 | 92 | 84 |
| Columbia SC | 3,250 | 43 | 787.00 | 41 | 74 | 67 |
| Greenville-Anderson-Mauldin SC | 2,711 | 51 | 787.00 | 41 | 69 | 61 |
| Memphis TN | 1,926 | 74 | 785.00 | 45 | 119 | 100 |
| Omaha NE | 2,265 | 63 | 780.65 | 46 | 28 | 8 |
| Council Bluffs IA | 2,085 | 70 | 780.65 | 46 | 14 | 1 |
| Chester Lancaster-York Counties SC | 1,810 | 79 | 780.00 | 48 | 30 | 10 |
| Oklahoma City OK | 5,512 | 15 | 778.68 | 49 | 59 | 49 |
| Birmingham-Hoover AL | 5,280 | 17 | 776.79 | 50 | 86 | 79 |

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260—Continued [Semi-Electric Hospital Bed]

| Area name | Size in square miles | Size rank | Maximum winning bid E0260 | Max E0260 bid rank | Average E0260 services per supplier ¹ | Volume rank (low to high) E0260 |
|---|----------------------|------------|---------------------------------|-----------------------|---|---------------------------------------|
| Chattanooga TN | 1,306 | 99 | 776.27 | 51 | 45 | 27 |
| Washington DC | 61 | 130 | 765.00 | 52 | 110 | 97 |
| Miami-Fort Lauderdale-West Palm Beach FL | 5,077 | 20 | 760.20 | 53 | 159 | 118 |
| Jacksonville FL | 3,201 | 45 | 752.90 | 54 | 115 | 99 |
| Jackson MS | 4,649 | 24 | 752.90 | 55 | 82 | 74 |
| Baton Rouge LA | 4,027 | 32 | 752.90 | 55 | 61 | 51 |
| South Haven-Olive Branch MS | 2,448 | 57 | 752.90 | 55 | 55 | 40 |
| Cape Coral-Fort Myers FL East St. Louis IL | 785 3,845 | 118 36 | 752.90 750.00 | 55 59 | 37 59 | 22 48 |
| Catoosa Dade-Walker Counties GA | 783 | 119 | 750.00 | 59 | 24 | 5 |
| Pittsburgh PA | 5,282 | 16 | 749.00 | 61 | 121 | 103 |
| Raleigh NC | 2,118 | 68 | 748.00 | 62 | 70 | 62 |
| Charleston-North Charleston SCAiken-Edgefield Counties SC | 2,588 1,571 | 54 90 | 748.00 748.00 | 62 62 | 60 56 | 50 43 |
| Syracuse NY | 2,385 | 61 | 748.00 | 65 | 50 | 34 |
| St. Louis MO | 5,267 | 18 | 739.22 | 66 | 57 | 45 |
| Nassau Kings Queens-Richmond Coun- | | | | _ | | |
| ties NY Titusvilla El | 522 | 126 | 739.09 | 67 | 253 | 126 |
| Palm Bay-Melbourne-Titusville FL Rockingham-Strafford Counties NH | 1,016 1,064 | 111 107 | 739.09 738.98 | 67 67 | 67 53 | 56 38 |
| Milwaukee-Waukesha-West Allis WI | 1,455 | 96 | 733.74 | 70 | 84 | 76 |
| Las Vegas-Henderson-Paradise NV | 1,578 | 89 | 733.01 | 71 | 47 | 31 |
| Providence RI | 1,034 | 109 | 728.84 | 72 | 63 | 55 |
| Huntington WV Dearborn Franklin Ohio-Union Counties | 1,570 | 92 | 728.75 | 73 | 54 | 39 |
| IN | 937 | 113 | 728.70 | 74 | 31 | 15 |
| Mercer County PA | 673 | 120 | 725.00 | 75 | 33 | 16 |
| Aurora-Elgin-Joliet IL | 2,727 | 50 | 720.00 | 76 77 | 120 | 102 |
| Gary IN Houston-The Woodlands-Sugar Land TX | 1,878 8,827 | 77 5 | 719.99 714.06 | 77 | 124 129 | 105 108 |
| Tulsa OK | 6,269 | 11 | 710.00 | 79 | 76 | 70 |
| Visalia-Porterville CA | 3,377 | 41 | 705.49 | 80 | 113 | 98 |
| San Francisco-Oakland-Hayward CA San Jose-Sunnyvale-Santa Clara CA | 2,471 2,679 | 56 53 | 705.49 705.49 | 80 80 | 92 30 | 85 13 |
| San Diego-Carlsbad CA | 4,207 | 28 | 705.49 | 80 | 30 | 11 |
| Cleveland-Elyria OH | 1,997 | 72 | 705.00 | 84 | 180 | 122 |
| New Orleans-Metairie LA | 2,422 | 60 | 705.00 | 84 | 126 | 106 |
| Pierce-St. Croix Counties WI Louisville-Jefferson County KY | 1,296 2,440 | 101 58 | 703.14 700.00 | 86 87 | 19 139 | 2 111 |
| Dayton OH | 1,706 | 83 | 700.00 | 87 | 103 | 92 |
| Cincinnati OH | 2,216 | 66 | 700.00 | 87 | 101 | 89 |
| Albany-Schenectady-Troy NY | 2,812 | 49 | 700.00 | 87 | 95 | 88 |
| Columbus OH Youngstown-Warren-Boardman OH | 4,797 1,030 | 22 110 | 700.00 700.00 | 87 87 | 87 63 | 80 54 |
| Dallas-Fort Worth-Arlington TX | 9,091 | 3 | 697.17 | 93 | 142 | 113 |
| Baltimore-Columbia-Towson MD | 2,948 | 47 | 695.52 | 94 | 190 | 123 |
| Asheville NC | 2,033 | 71 | 691.83 | 95 | 51 | 35 |
| Bakersfield CACalvert Charles-Prince Georges Counties | 8,132 | 6 | 690.00 | 96 | 24 | 7 |
| MD | 1,154 | 104 | 688.85 | 97 | 101 | 91 |
| Suffolk County NY | 912 | 114 | 687.05 | 98 | 168 | 120 |
| Port Chester-White Plains-Yonkers NY | 834 900 | 116 | 687.05 683.00 | 98 100 | 129 | 109 |
| Akron OHPhiladelphia PA | 2,156 | 115 67 | 682.71 | 100 | 90 308 | 83 129 |
| Buffalo-Cheektowaga-Niagara Falls NY | 1,565 | 93 | 680.00 | 102 | 90 | 82 |
| Rochester NY | 3,266 | 42 | 680.00 | 102 | 77 | 72 |
| Jersey City-Newark NJ | 1,926 | 74 | 675.00 | 104 | 258 | 128 |
| Elizabeth-Lakewood-New Brunswick NJ Detroit-Warren-Dearborn MI | 2,239 3,888 | 64 35 | 675.00 675.00 | 104 104 | 258 216 | 127 125 |
| Flint MI | 637 | 121 | 675.00 | 104 | 83 | 75 |
| Grand Rapids-Wyoming MI | 4,053 | 31 | 675.00 | 104 | 76 | 69 |
| Arlington-Alexandria-Reston VA | 3,226 | 44 | 675.00 | 104 | 72 | 64 |
| Richmond VA | 4,897 5,004 | 21 | 675.00 | 104 | 49 151 | 32 115 |
| Sacramento-Roseville-Arden-Arcade CA Orange County CA | 5,094 791 | 19 117 | 674.00 674.00 | 111 111 | 151 68 | 115 59 |
| Oxnard-Thousand Oaks-Ventura CA | 1,290 | 102 | 674.00 | 111 | 56 | 44 |
| Stockton-Lodi CA | 1,391 | 98 | 674.00 | 111 | 37 | 21 |

TABLE 25—MAXIMUM BID AMOUNTS IN ROUND 1 2017 AND ROUND 2 RECOMPETE FOR CODE E0260—Continued [Semi-Electric Hospital Bed]

| Area name | Size in square miles | Size rank | Maximum winning bid E0260 | Max E0260 bid rank | Average E0260 services per supplier ¹ | Volume rank (low to high) E0260 |
|---|-------------------------|-----------|---------------------------------|-----------------------|---|---------------------------------------|
| San Antonio-New Braunfels TX | 7,313 | 8 | 671.50 | 115 | 29 | 9 |
| Camden NJ | 1,674 | 84 | 670.00 | 116 | 209 | 124 |
| Bronx-Manhattan NY | 65 | 129 | 670.00 | 116 | 150 | 114 |
| Virginia Beach-Norfolk-Newport News VA | 2,089 | 69 | 670.00 | 116 | 77 | 71 |
| North Port-Sarasota-Bradenton FL | 1,299 | 100 | 667.98 | 119 | 45 | 28 |
| Toledo OH | 1,618 | 85 | 664.58 | 120 | 55 | 41 |
| Covington-Florence-Newport KY | 1,400 | 97 | 658.46 | 121 | 55 | 42 |
| Lake-McHenry Counties IL | 1,047 | 108 | 629.90 | 122 | 107 | 95 |
| Allentown-Bethlehem-Easton PA | 1,096 | 106 | 625.00 | 123 | 172 | 121 |
| Poughkeepsie-Newburgh-Middletown NY | 1,607 | 86 | 625.00 | 123 | 67 | 58 |
| Kenosha County WI | 272 | 128 | 618.78 | 125 | 23 | 4 |
| Bristol County MA | 553 | 125 | 600.00 | 126 | 105 | 94 |
| Springfield MA | 1,844 | 78 | 574.29 | 127 | 121 | 104 |
| Little Rock-North Little Rock-Conway AR | 4,085 | 30 | 574.29 | 127 | 90 | 81 |
| Tucson AZ | 3,675 | 38 | 574.29 | 127 | 42 | 26 |
| Vancouver WA | 2,285 | 62 | 574.29 | 127 | 40 | 25 |

¹ 2016 allowed services.

We found no correlation between the size of the areas and/or average volume per supplier and maximum bid amounts for code E0260. The lowest volume CBA (Council Bluffs, Iowa) had the 46th highest maximum bid for E0260 and the second lowest volume CBA (Pierce-St. Croix Counties Wisconsin) had the 86th highest maximum bid for E0260. The highest maximum bid for E0260 was from the 7,437 square mile area for Salt Lake City, Utah (the 7th largest area), but the second highest maximum bid for

E0260 was from the 1,585 square mile area for Ocala, Florida (the 88th largest area).

We also analyzed the maximum bids for E0260 for states with at least 7 CBAs to see if there was any correlation between maximum bid amounts and area size, average volume per supplier, or number of suppliers and did not see any correlation between the maximum bids and these factors. California has 12 CBAs ranging in size from 791 to 8,900 square miles. Bakersfield, one of the

CBAs, has the second largest service area (8,132 square miles) and lowest average volume per supplier for E0260 in 2016 (24) in California, but the maximum winning bid for E0260 for Bakersfield was lower than the maximum winning bids for seven of the eleven other CBAs, all having smaller service areas as well, with the exception of Riverside (8,900 square miles). See Table 26.

TABLE 26—ROUND 1 2017 AND ROUND 2 RECOMPETE CALIFORNIA CBA COMPARISON AND MAXIMUM BIDS FOR E0260

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|---------------------|--------------------------------|------------|---|--|--|---------------------------|
| Bakersfield | 8,132 | 839,631 | 462 | 19 | 24 | \$690.00 |
| Fresno | 5,958 | 930,450 | 571 | 19 | 30 | 816.78 |
| San Diego | 4,207 | 3,095,313 | 1,360 | 46 | 30 | 705.49 |
| San Jose | 2,679 | 1,836,911 | 913 | 30 | 30 | 705.49 |
| Stockton-Lodi | 1,391 | 685,306 | 586 | 16 | 37 | 674.00 |
| Riverside | 8,900 | 4,224,851 | 2,838 | 54 | 53 | 920.00 |
| Oxnard | 1,290 | 823,318 | 1,124 | 20 | 56 | 674.00 |
| Orange County | 791 | 3,010,232 | 2,596 | 38 | 68 | 674.00 |
| San Francisco | 2,471 | 4,335,391 | 5,729 | 62 | 92 | 705.49 |
| Los Angeles County | 2,232 | 9,818,605 | 11,509 | 106 | 109 | 840.60 |
| Visalia-Porterville | 3,377 | 442,179 | 907 | 8 | 113 | 705.49 |
| Sacramento | 5,094 | 2,149,127 | 5,434 | 36 | 151 | 674.00 |

Florida has 10 CBAs ranging in size from 785 to 5,077 square miles. Ocala, one of the CBAs, has the lowest volume per supplier and the highest maximum bid in Florida. However, North Point and Deltona have much lower maximum bids for E0260 but only slightly higher volume and number of

suppliers and are the same size as the Ocala CBA. See Table 27.

TABLE 27—ROUND 1 2017 AND ROUND 2 RECOMPETE FLORIDA CBA COMPARISON AND MAXIMUM BIDS FOR E0260

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|-----------------------|--------------------------------|------------|---|--|--|---------------------------|
| Ocala | 1,585 | 331,303 | 1,195 | 36 | 33 | \$1,325.00 |
| Cape Coral-Fort Myers | 785 | 618,754 | 1,189 | 32 | 37 | 752.90 |
| North Port-Sarasota | 1,299 | 702,281 | 2,177 | 48 | 45 | 667.98 |
| Deltona | 1,586 | 590,289 | 2,223 | 49 | 45 | 798.88 |
| Orlando | 3,478 | 2,134,406 | 6,593 | 98 | 67 | 873.47 |
| Palm Bay-Melbourne | 1,016 | 543,376 | 2,416 | 36 | 67 | 739.09 |
| Lakeland | 1,798 | 602,095 | 2,636 | 37 | 71 | 798.88 |
| Tampa-St. Petersburg | 2,513 | 2,783,243 | 8,059 | 95 | 85 | 850.00 |
| Jacksonville | 3,201 | 1,345,596 | 5,163 | 45 | 115 | 752.90 |
| Miami | 5,077 | 5,564,657 | 20,183 | 127 | 159 | 760.20 |

New York has 9 CBAs ranging in size from 65 to 3,266 square miles. Syracuse, one of the CBAs, has the lowest volume and highest maximum bid in New York for E0260. By contrast, the Nassau CBA has a much higher volume for E0260 and a smaller service area than the Syracuse CBA, but a maximum bid for

E0260 that is very close to the maximum bid for E0260 for the Syracuse CBA. See Table 28.

TABLE 28—ROUND 2 RECOMPETE NEW YORK CBA COMPARISON AND MAXIMUM BIDS FOR E0260

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|---------------------|--------------------------------|------------|---|--|--|---------------------------|
| Syracuse | 2,385 | 662,577 | 1,599 | 32 | 50 | \$742.50 |
| Poughkeepsie | 1,607 | 670,301 | 2,291 | 34 | 67 | 625.00 |
| Rochester | 3,266 | 1,079,671 | 2,382 | 31 | 77 | 680.00 |
| Buffalo | 1,565 | 1,135,509 | 1,983 | 22 | 90 | 680.00 |
| Albany | 2,812 | 870,716 | 2,854 | 30 | 95 | 700.00 |
| Port Chester | 834 | 1,360,510 | 6,591 | 51 | 129 | 687.05 |
| Bronx-Manhattan | 65 | 2,970,981 | 9,884 | 66 | 150 | 670.00 |
| Suffolk County | 912 | 1,493,350 | 6,231 | 37 | 168 | 687.05 |
| Nassau Kings Queens | 522 | 6,543,684 | 25,839 | 102 | 253 | 739.09 |

Ohio has 7 CBAs ranging in size from 900 to 4,797 square miles. Four of the

CBAs have the same maximum bid for E0260 (\$700), yet the areas are not

similar in size, volume, or number of suppliers. See Table 29.

TABLE 29—ROUND 1 2017 AND ROUND 2 RECOMPETE OHIO CBA COMPARISON AND MAXIMUM BIDS FOR E0260

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|------------|--------------------------------|------------|---|--|--|---------------------------|
| Toledo | 1,618 | 651,429 | 1,649 | 30 | 55 | \$664.58 |
| Youngstown | 1,030 | 449,130 | 1,199 | 19 | 63 | 700.00 |
| Columbus | 4,797 | 1,901,974 | 5,409 | 62 | 87 | 700.00 |
| Akron | 900 | 703,200 | 2,350 | 26 | 90 | 683.00 |
| Cincinnati | 2,216 | 1,625,406 | 4,530 | 45 | 101 | 700.00 |
| Dayton | 1,706 | 841,502 | 3,705 | 36 | 103 | 700.00 |
| Cleveland | 1,997 | 2,077,245 | 10,623 | 59 | 180 | 705.00 |

Finally, Texas has 7 CBAs ranging in size from 1,013 to 9,091 square miles. The San Antonio CBA has the lowest volume for E0260 and is a large area, but

has the lowest maximum bid amount for E0260 in Texas. The McAllen CBA has the highest maximum bid amount for E0260, but is much smaller and has a

much higher average volume per supplier for E0260 than the San Antonio CBA. See Table 30.

TABLE 30—ROUND 1 2017 AND ROUND 2 RECOMPETE TEXAS CBA COMPARISON AND MAXIMUM BIDS FOR E0260

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|-------------|--------------------------------|------------|---|--|--|---------------------------|
| San Antonio | 7,313 | 2,142,508 | 1,026 | 35 | 29 | \$671.50 |

TABLE 30—ROUND 1 2017 AND ROUND 2 RECOMPETE TEXAS CBA COMPARISON AND MAXIMUM BIDS FOR E0260—Continued

| Area | Service area (square miles) | Population | Allowed services in 2016 (E0260) | Number of suppliers in 2016 (E0260) | Average allowed services per supplier | Maximum bid (E0260) |
|----------------------|--------------------------------|------------|---|--|--|---------------------------|
| Beaumont-Port Arthur | 3,034 | 403,190 | 894 | 24 | 37 | 800.00 |
| Austin | 4,220 | 1,716,289 | 2,599 | 45 | 58 | 800.00 |
| El Paso | 1,013 | 800,647 | 1,110 | 15 | 74 | 800.00 |
| McAllen | 1,571 | 774,773 | 2,279 | 18 | 127 | 950.00 |
| Houston | 8,827 | 5,946,800 | 11,353 | 88 | 129 | 714.06 |
| Dallas | 9,091 | 6,417,724 | 14,362 | 101 | 142 | 697.17 |

We did not find any correlation between maximum winning bid amounts for code E0260 and the size of a service area or between maximum winning bid amounts for code E0260 and the volume of items and services furnished by suppliers in various areas. Table 31 lists the 130 maximum bids

Table 31 lists the 130 maximum bids in Round 1 2017 and Round 2 Recompete for code E1390 (oxygen concentrators and portable oxygen contents or tanks).

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390

[Oxygen concentrator and portable contents/tanks]

| Area name | Size in square miles | Size rank | Maximum winning bid E1390 | Max E1390 bid rank | Average E1390 services per supplier ¹ | Volume rank (low to high) E1390 |
|---|----------------------|-----------|---------------------------------|-----------------------|---|---------------------------------------|
| Cape Coral-Fort Myers, FL | 785 | 118 | \$135.50 | 1 | 108 | 7 |
| Seattle-Tacoma-Bellevue, WA | 5,872 | 14 | 134.17 | 2 | 222 | 79 |
| Birmingham-Hoover, AL | 5,280 | 17 | 132.52 | 3 | 174 | 49 |
| Hartford-West Hartford-East Hartford, CT | 1,515 | 94 | 130.28 | 4 | 287 | 108 |
| Albuquerque, NM | 6,287 | 10 | 123.00 | 5 | 224 | 81 |
| Jeffersonville-New Albany, IN | 1,709 | 82 | 117.60 | 6 | 278 | 102 |
| Gary, IN | 1,878 | 77 | 117.60 | 6 | 279 | 103 |
| Indianapolis-Carmel-Anderson, IN | 3,994 | 33 | 115.00 | 8 | 357 | 122 |
| North Port-Sarasota-Bradenton, FL | 1,299 | 100 | 110.50 | 9 | 136 | 19 |
| Nashville-Davidson-Murfreesboro-Frank- | ,,_,, | | | | | |
| lin. TN | 6.036 | 12 | 109.00 | 10 | 185 | 57 |
| Miami-Fort Lauderdale-West Palm | 0,000 | | 100.00 | | 100 | 0. |
| Beach, FL | 5,077 | 20 | 109.00 | 10 | 199 | 65 |
| Salt Lake City, UT | 7.473 | 7 | 106.00 | 12 | 375 | 126 |
| Ocala, FL | 1,585 | 88 | 106.00 | 12 | 108 | 7 |
| Charlotte-Concord-Gastonia, NC | 3,788 | 37 | 106.00 | 12 | 243 | 89 |
| Kansas City, MO | 4,572 | 25 | 106.00 | 12 | 315 | 115 |
| Wichita, KS | 4,149 | 29 | 106.00 | 12 | 412 | 130 |
| Knoxville. TN | 3,501 | 39 | 106.00 | 12 | 217 | 76 |
| Portland-Hillsboro-Beaverton, OR | 4,399 | 26 | 106.00 | 12 | 132 | 16 |
| McAllen-Edinburg-Mission, TX | 1,571 | 90 | 106.00 | 12 | 80 | 2 |
| Colorado Springs, CO | 2,684 | 52 52 | 106.00 | 12 | 368 | 124 |
| Phoenix-Mesa-Scottsdale, AZ | 12,036 | 1 | 106.00 | 12 | 168 | 44 |
| Riverside-San Bernardino-Ontario, CA | 8,900 | 4 | 106.00 | 12 | 188 | 61 |
| Bridgeport-Stamford-Norwalk, CT | 625 | 122 | 106.00 | 12 | 234 | 84 |
| Tampa-St. Petersburg-Clearwater, FL | 2,513 | 55 | 106.00 | 12 | 202 | 67 |
| Boise City, ID | 11,766 | 2 | 106.00 | 12 | 147 | 24 |
| Los Angeles County, CA | 2,232 | 65 | 106.00 | 12 | 202 | 67 |
| New Haven-Milford, CT | 605 | 123 | 106.00 | 12 | 237 | 87 |
| • | 2,424 | 59 | 106.00 | 12 | 349 | 121 |
| Boston-Cambridge-Quincy, MA Kansas City-Overland Park-Ottawa, KS | 2,424 | 48 | 106.00 | 12 | 275 | 100 |
| , | | 34 | 106.00 | 12 | 275 365 | 123 |
| Denver-Aurora-Lakewood, CO | 3,906 | - | | | | |
| Chicago-Naperville-Arlington Heights, IL | 1,273 | 103 | 106.00 106.00 | 12 12 | 377 | 127 105 |
| Fresno, CA | 5,958 | 13 95 | 106.00 | 12 | 280 226 | 82 |
| Worcester, MA | 1,511 | 23 | | | - | 30 |
| Minneapolis-St. Paul-Bloomington, MN | 4,731 1.013 | 23 112 | 106.00 106.00 | 12 12 | 152 178 | 52 |
| El Paso, TX | , | | | | - | 22 |
| Austin-Round Rock, TX | 4,220 | 27 | 106.00 | 12 | 143 | 47 |
| Beaumont-Port Arthur, TX | 3,034 | 46 | 106.00 | 12 | 171 | |
| Lakeland-Winter Haven, FL Deltona-Daytona Beach-Ormond Beach, | 1,798 | 80 | 106.00 | 12 | 115 | 10 |
| FL | 1,586 | 87 | 106.00 | 12 | 123 | 13 |
| Silver Spring-Rockville-Bethesda, MD | 1,152 | 105 | 106.00 | 12 | 132 | 16 |
| Atlanta-Sandy Springs-Roswell, GA | 7,275 | 9 | 106.00 | 12 | 236 | 86 |
| Columbia, SC | 3,250 | 43 | 106.00 | 12 | 186 | 58 |

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390—Continued [Oxygen concentrator and portable contents/tanks]

| | 1- 73- | centrator and por | | • | | |
|--|----------------------|-------------------|---------------------------------|-----------------------|---|---------------------------------------|
| Area name | Size in square miles | Size rank | Maximum winning bid E1390 | Max E1390 bid rank | Average E1390 services per supplier ¹ | Volume rank (low to high) E1390 |
| Memphis, TN | 1,926 | 74 | 106.00 | 12 | 297 | 111 |
| Omaha, NE | 2,265 | 63 | 106.00 | 12 | 170 | 46 |
| Council Bluffs, IA | 2,085 | 70 | 106.00 | 12 | 148 | 26 |
| Oklahoma City, OK | 5,512 | 15 | 106.00 | 12 | 286 | 106 |
| Chattanooga, TN | 1,306 | 99 | 106.00 | 12 | 176 | 51 |
| Washington, DC | 61 | 130 | 106.00 | 12 | 113 | 9 |
| Jacksonville, FL | 3,201 | 45 | 106.00 | 12 | 187 | 59 |
| Jackson, MS | 4,649 | 24 | 106.00 | 12 | 150 | 27 |
| Baton Rouge, LA | 4,027 | 32 | 106.00 | 12 | 166 | 39 |
| South Haven-Olive Branch, MS | 2,448 | 57 | 106.00 | 12 | 214 | 74 |
| East St. Louis, IL | 3,845 | 36 | 106.00 | 12 | 258 | 92 |
| Pittsburgh, PA | 5,282 | 16 | 106.00 | 12 | 327 | 120 |
| Charleston-North Charleston, SC | 2,588 | 54 90 | 106.00 106.00 | 12 12 | 153 96 | 31 3 |
| Aiken-Edgefield Counties, SCSt. Louis, MO | 1,571 5,267 | 18 | 106.00 | 12 | 315 | 115 |
| Nassau Kings Queens-Richmond Coun- | 5,207 | 10 | 100.00 | 12 | 313 | 113 |
| ties, NY | 522 | 126 | 106.00 | 12 | 216 | 75 |
| Palm Bay-Melbourne-Titusville, FL | 1,016 | 111 | 106.00 | 12 | 157 | 34 |
| Rockingham-Strafford Counties, NH | 1,064 | 107 | 106.00 | 12 | 197 | 64 |
| Milwaukee-Waukesha-West Allis, WI | 1,455 | 96 | 106.00 | 12 | 268 | 99 |
| Providence, RI | 1,034 | 109 | 106.00 | 12 | 221 | 77 |
| Huntington, WV | 1,570 | 92 | 106.00 | 12 | 223 | 80 |
| Dearborn Franklin Ohio-Union Counties, | | | | | | |
| IN | 937 | 113 | 106.00 | 12 | 106 | 5 |
| Aurora-Elgin-Joliet, IL | 2,727 | 50 | 106.00 | 12 | 191 | 62 |
| Houston-The Woodlands-Sugar Land, TX | 8,827 | 5 | 106.00 | 12 | 207 | 69 |
| Tulsa, OK | 6,269 | 11 | 106.00 | 12 | 226 | 82 |
| Visalia-Porterville, CA | 3,377 | 41 | 106.00 | 12 | 398 | 128 |
| San Francisco-Oakland-Hayward, CA | 2,471 | 56 | 106.00 | 12 | 166 | 39 |
| San Jose-Sunnyvale-Santa Clara, CA | 2,679 | 53 | 106.00 | 12 | 130 | 15 |
| San Diego-Carlsbad, CA | 4,207 1,997 | 28 72 | 106.00 106.00 | 12 12 | 159 | 35 129 |
| Cleveland-Elyria, OH New Orleans-Metairie, LA | 2,422 | 60 | 106.00 | 12 | 407 160 | 36 |
| Pierce-St. Croix Counties, WI | 1,296 | 101 | 106.00 | 12 | 72 | 1 |
| Dayton, OH | 1,706 | 83 | 106.00 | 12 | 235 | 85 |
| Cincinnati, OH | 2,216 | 66 | 106.00 | 12 | 311 | 112 |
| Albany-Schenectady-Troy, NY | 2,812 | 49 | 106.00 | 12 | 263 | 94 |
| Columbus, OH | 4,797 | 22 | 106.00 | 12 | 199 | 65 |
| Dallas-Fort Worth-Arlington, TX | 9,091 | 3 | 106.00 | 12 | 262 | 93 |
| Baltimore-Columbia-Towson, MD | 2,948 | 47 | 106.00 | 12 | 324 | 118 |
| Bakersfield, CA | 8,132 | 6 | 106.00 | 12 | 164 | 38 |
| Calvert-Charles-Prince Georges Coun- | | | | | | |
| ties, MD | 1,154 | 104 | 106.00 | 12 | 178 | 52 |
| Suffolk County, NY | 912 | 114 | 106.00 | 12 | 208 | 70 |
| Port Chester-White Plains-Yonkers, NY | 834 | 116 | 106.00 | 12 | 153 | 31 |
| Philadelphia, PA | 2,156 | 67 | 106.00 | 12 | 326 | 119 |
| Buffalo-Cheektowaga-Niagara Falls, NY Rochester, NY | 1,565 | 93 | 106.00 | 12 | 286 | 106 |
| Detroit-Warren-Dearborn, MI | 3,266 3,888 | 42 35 | 106.00 106.00 | 12 12 | 171 322 | 47 117 |
| Grand Rapids-Wyoming, MI | 4,053 | 31 | 106.00 | 12 | 183 | 54 |
| Arlington-Alexandria-Reston, VA | 3,226 | 44 | 106.00 | 12 | 166 | 39 |
| Richmond, VA | 4,897 | 21 | 106.00 | 12 | 275 | 100 |
| Sacramento-Roseville-Arden-Arcade, CA | 5,094 | 19 | 106.00 | 12 | 210 | 72 |
| Orange County, CA | 791 | 117 | 106.00 | 12 | 134 | 18 |
| Oxnard-Thousand Oaks-Ventura, CA | 1,290 | 102 | 106.00 | 12 | 140 | 20 |
| San Antonio-New Braunfels, TX | 7,313 | 8 | 106.00 | 12 | 210 | 72 |
| Bronx-Manhattan, NY | 65 | 129 | 106.00 | 12 | 97 | 4 |
| Virginia Beach-Norfolk-Newport News, | | 2 | | | | · |
| VA | 2,089 | 69 | 106.00 | 12 | 253 | 91 |
| Covington-Florence-Newport, KY | 1,400 | 97 | 106.00 | 12 | 167 | 42 |
| Lake-McHenry Counties, IL | 1,047 | 108 | 106.00 | 12 | 183 | 55 |
| Kenosha County, WI | 272 | 128 | 106.00 | 12 | 161 | 37 |
| Bristol County, MA | 553 | 125 | 106.00 | 12 | 264 | 97 |
| Springfield, MA | 1,844 | 78 | 106.00 | 12 | 252 | 90 |
| Tucson, AZ | 3,675 | 38 | 106.00 | 12 | 141 | 21 |
| Vancouver, WA | 2,285 | 62 | 106.00 | 12 | 121 | 11 |
| Raleigh, NC | 2,118 | 68 | 105.00 94.00 | 105 | 127 | 14 |
| Asheville, NC | 2,033 | 71 | | 106 | 312 | 114 |

TABLE 31—MAXIMUM BID AMOUNTS FOR HCPCS CODE E1390—Continued

[Oxygen concentrator and portable contents/tanks]

| Area name | Size in square miles | Size rank | Maximum winning bid E1390 | Max E1390 bid rank | Average E1390 services per supplier ¹ | Volume rank (low to high) E1390 |
|--|----------------------|-----------|---------------------------------|-----------------------|---|---------------------------------------|
| Honolulu, HI | 601 | 124 | 92.66 | 107 | 107 | 6 |
| Las Vegas-Henderson-Paradise, NV | 1.578 | 89 | 92.27 | 108 | 191 | 62 |
| Orlando-Kissimmee-Sanford, FL | 3,478 | 40 | 92.00 | 109 | 175 | 50 |
| Greensboro-High Point, NC | 1,994 | 73 | 86.84 | 110 | 169 | 45 |
| Poughkeepsie-Newburgh-Middletown, | , | | | | | |
| NY | 1.607 | 86 | 85.35 | 111 | 147 | 24 |
| Augusta-Richmond County, GA | 1,909 | 76 | 85.00 | 112 | 155 | 33 |
| Allentown-Bethlehem-Easton, PA | 1,096 | 106 | 85.00 | 112 | 263 | 94 |
| Flint, MI | 637 | 121 | 84.29 | 114 | 150 | 27 |
| Greenville-Anderson-Mauldin, SC | 2,711 | 51 | 83.44 | 115 | 263 | 94 |
| Chester Lancaster-York Counties, SC | 1,810 | 79 | 83.44 | 115 | 150 | 27 |
| Scranton-Wilkes-Barre-Hazleton, PA | 1,747 | 81 | 83.00 | 117 | 311 | 112 |
| Louisville-Jefferson County, KY | 2,440 | 58 | 83.00 | 117 | 373 | 125 |
| Little Rock-North Little Rock-Conway, AR | 4,085 | 30 | 83.00 | 117 | 279 | 103 |
| Stockton-Lodi, CA | 1,391 | 98 | 82.15 | 120 | 122 | 12 |
| Wilmington, DE | 426 | 127 | 82.00 | 121 | 209 | 71 |
| Mercer County, PA | 673 | 120 | 82.00 | 121 | 143 | 22 |
| Jersey City-Newark, NJ | 1,926 | 74 | 82.00 | 121 | 237 | 87 |
| Camden, NJ | 1,674 | 84 | 82.00 | 121 | 287 | 108 |
| Youngstown-Warren-Boardman, OH | 1,030 | 110 | 81.41 | 125 | 187 | 59 |
| Akron, OH | 900 | 115 | 81.41 | 125 | 167 | 42 |
| Syracuse, NY | 2,385 | 61 | 81.00 | 127 | 265 | 98 |
| Elizabeth-Lakewood-New Brunswick, NJ | 2,239 | 64 | 81.00 | 127 | 296 | 110 |
| Catoosa Dade-Walker Counties, GA | 783 | 119 | 79.80 | 129 | 221 | 77 |
| Toledo, OH | 1,618 | 85 | 79.80 | 129 | 183 | 55 |

¹ 2016 allowed services.

Again, we found no correlation between area size and/or average volume for E1390 per supplier and maximum bid amounts. In addition, CBAs that had the highest maximum winning bids for code E0260 did not always have the highest maximum winning bids for code E1390. For example, the Cape Coral-Fort Myers. Florida CBA had the highest maximum winning bid for E1390, but was tied for the 55th highest maximum winning bid for E0260. In many cases, national chain suppliers for oxygen bid the same amount in every area. For oxygen and oxygen equipment (E1390), there were six national chain suppliers that submitted the same winning bid amounts in at least 33 different CBAs and four suppliers that submitted the same winning bid amounts in at least 67 different CBAs. One of these suppliers submitted the maximum winning bid for E1390 of \$106 in 93 different CBAs.

Maximum bid amounts can be bid amounts from a single supplier (the supplier submitting the pivotal bid), which may or may not reflect the costs of other suppliers and don't seem to show any pattern from area to area in terms of some areas always having the highest maximum bids for items and other areas always having the lowest maximum winning bids for items. The maximum winning bids for items show

no correlation with area size, volume, or number of suppliers. In some cases, the maximum bid amount is the same in dozens of different CBAs across the country. The maximum bids for lower weight items are also impacted by unbalanced bidding, whereby the suppliers bid higher amounts for these items knowing that they will have little impact on their composite bid and chances for winning.

3. Travel Distance Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the average travel distances associated with furnishing items and services in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We first examined the average travel distances in CBAs versus non-CBAs by analyzing differences in the geographic size in square miles of CBAs versus non-CBAs consisting of MSAs and micropolitan statistical areas (micro areas). The majority of items subject to the fee schedule adjustments are furnished in these non-CBAs.

The U.S. Office of Management and Budget (OMB) delineates MSAs and micro areas, which are referred to collectively as "core based statistical areas" (CBSAs). OMB set the standards for delineating MSAs and micro areas in the notice published on June 28, 2010 in the Federal Register, titled "2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas" (75 FR 37245). The general concept of the MSA and micro area is that of a core area containing a substantial population nucleus, together with adjacent communities having a higher degree of economic and social integration with that core. CBSAs consist of counties and equivalent entities throughout the U.S. and Puerto Rico (75 FR 37249). A CBSA is categorized based on the population of the largest urban area (urbanized area or urban cluster) within the CBSA (75 FR 37250). Each CBSA must have a Census Bureau delineated urbanized area of at least 50,000 population or a Census Bureau delineated urban cluster of at least 10,000 population (75 FR 37249). An urbanized area is a statistical geographic entity delineated by the U.S. Census Bureau, consisting of densely settled census tracts and blocks and adjacent densely settled territory that together contain at least 50,000 people (75 FR 37252). An urban cluster is a statistical geographic entity delineated by the U.S. Census Bureau, consisting of densely settled census tracts and blocks and adjacent densely settled territory that together contain at least 2,500

people (75 FR 37252). MSAs contain at least one urbanized area that has a population of at least 50,000; micro areas contain at least one urban cluster that has a population of at least 10,000 and less than 50,000 (75 FR 37252).

We compared the average size of the different areas nationally and by Bureau of Economic Analysis (BEA) region. We also computed the weighted average size of the different areas nationally and by region, weighted by total population. The CBAs have much larger service areas than the non-CBA MSA and micro

areas. It is also worth noting that our current definition of rural area for the purposes of fee schedule adjustments in non-CBAs includes micro areas (in general, a rural area is currently defined at 42 CFR 414.202 as any zip code area where at least 50 percent of the area is outside a MSA or with a low population density that was excluded from a CBA).

Under the CBP, a contract supplier is required to deliver items to any beneficiary in the CBA that requests service. The size of CBAs can be compared to the size of non-CBAs to indicate how far a supplier located in or near the areas may have to travel to serve beneficiaries located in the various areas. As shown in Table 32, the average size of CBAs in each of the eight BEA regions is larger than the average size of both non-rural areas and rural areas classified as micro areas by OMB, areas where competitive bidding, for the most part, not yet been implemented, and where the vast majority of items are furnished in the non-CBAs.

TABLE 32—AVERAGE SIZE OF AREA [Square miles]

| BEA region | СВА | MSA | Micro |
|----------------|-------|-------|-------|
| New England | 1,241 | 1,175 | 968 |
| Mideast | 1,659 | 833 | 859 |
| Great Lakes | 2,061 | 942 | 638 |
| Plains | 3,700 | 1,880 | 1,029 |
| Southeast | 2,776 | 1,218 | 681 |
| Southwest | 5,737 | 3,637 | 1,992 |
| Rocky Mountain | 6,457 | 3,025 | 3,002 |
| Far West | 3,791 | 2,308 | 3,776 |
| Average | 3,428 | 1,877 | 1,618 |

The average non-CBA MSA size is 55 percent of the average CBA size and the average non-CBA micro area size is 47 percent of the average CBA size. As shown in Table 33, when weighting the

average size of the areas based on U.S. Census total resident 2010 population numbers, the differences in the average size of the areas is similar to the differences noted in Table 32. The

weighted average non-CBA MSA size is 57 percent of the weighted average CBA size and the weighted average non-CBA micro area size is 43 percent of the weighted average CBA size.

TABLE 33—AVERAGE SIZE OF AREA (SQUARE MILES) WEIGHTED BY POPULATION

| BEA region | CBA | MSA | Micro |
|----------------|-------|-------|-------|
| BEA Region | CBA | MSA | Micro |
| New England | 1,624 | 1,273 | 1,094 |
| Mideast | 1,718 | 937 | 1,016 |
| Great Lakes | 2,707 | 1,875 | 711 |
| Plains | 4,371 | 3,169 | 1,157 |
| Southeast | 5,780 | 1,517 | 911 |
| Southwest | 7,917 | 3,510 | 2,355 |
| Rocky Mountain | 5,559 | 3,934 | 3,494 |
| Far West | 3,833 | 2,749 | 3,582 |
| Average | 4,189 | 2,371 | 1,790 |

The size of the CBAs are much larger than the size of the non-CBA MSAs and micro areas where most of the items subject to the fee schedule adjustments are furnished. The contract suppliers must serve every part of these areas and have much larger travel distances on average than suppliers in both non-CBA urban areas (MSAs) and non-CBA rural areas (areas outside MSAs).

The data in Table 34 shows what percentage of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where the items and services are furnished (that is, the percentage of suppliers located in the same area as the beneficiary). We separated the data by CBA, and then non-CBA MSA, micro area, or Outside Core Based Statistical

Area (OCBSA), which are counties that do not qualify for inclusion in a CBSA. The data in Table 34 shows that the majority of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where these items and services are furnished.

TABLE 34—PERCENTAGE OF ITEMS AND SERVICES IN 2016 FURNISHED BY SUPPLIERS LOCATED IN THE SAME AREA AS THE BENEFICIARY

| Beneficiary area | Hospital beds (%) | Oxygen (%) | All items (%) |
|------------------|-------------------|---------------|---------------|
| CBAs | 68 | 77 | 64 |

TABLE 34—PERCENTAGE OF ITEMS AND SERVICES IN 2016 FURNISHED BY SUPPLIERS—Continued LOCATED IN THE SAME AREA AS THE BENEFICIARY

| Beneficiary area | Hospital beds (%) | Oxygen (%) | All items (%) |
|---|-------------------|---------------|---------------|
| Non-CBA MSAs Non-CBA Micro Areas Non-CBA OCBSAs | 68 | 63 | 65 |
| | 64 | 61 | 61 |
| | 78 | 82 | 81 |

We also compared the average travel distances for suppliers in the different areas using claims data for items and services subject to the fee schedule adjustments. For each allowed DME item and service, we used the shortest distance between the coordinates of the beneficiary's residential ZIP code and those of the supplier's ZIP code on the surface of a globe as a proxy of DME delivery distance. In addition, we prioritized 9-digit ZIP codes over 5-digit ZIP codes when determining the coordinates. The results in Table 35 are for hospital beds and oxygen and oxygen equipment, items that are most likely to be delivered locally by suppliers using company vehicles.

TABLE 35—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON CLAIMS FOR 2016

| Beneficiary area | Hospital beds | Oxygen |
|--|----------------------|----------------------|
| CBAs Non-CBA MSAs Non-CBA Micro Areas Non-CBA OCBSAs | 62 35 30 34 | 79 54 49 57 |

These results indicate that the average travel distances in CBAs are much greater than the average travel distances in all non-CBAs, but the data may be skewed by claims for suppliers that put a billing address on the claim that is not the address of the location that furnished the item (either a different location or a subcontractor). The data may also be skewed by claims where the beneficiary receives the item from a supplier in a different area because he or she is travelling (for example,

"snowbirds"). To account for this, we excluded data for claims where the beneficiary address was more than two states away from the supplier location on the claim form, as these are likely claims where the item was delivered from a different location or by a subcontractor, or were claims for traveling beneficiaries (that is, snowbirds and other beneficiaries receiving items from suppliers in locations other than their permanent residence). We also excluded data for suppliers with multiple

locations that always put the same address on all of their claims. When using data for this restricted population (beneficiaries receiving items from suppliers in same or adjoining states) and these restricted suppliers (all suppliers except those with multiple locations that always bill from the same location), the results on average distances are significant, as shown in Table 36 for hospital beds, oxygen and oxygen equipment, and all items subject to the fee schedule adjustments.

TABLE 36—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY
BASED ON RESTRICTED CLAIMS FOR 2016 1

| Beneficiary area | Hospital beds | Oxygen | All items |
|--|---------------|--------|-----------|
| CBAs Non-CBA MSAs Non-CBA Micro Areas Non-CBA OCBSAs | 25 | 21 | 27 |
| | 22 | 19 | 24 |
| | 23 | 21 | 27 |
| | 27 | 30 | 36 |

¹ Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

Based on these results, the average distances from the supplier to the beneficiary in the CBAs are still greater than the average distances from the supplier to the beneficiary in the non-CBA MSAs and micro areas where most of the items subject to the fee schedule adjustments are furnished. However, the average distances for other rural areas (areas outside both MSAs and micro areas) are slightly greater than the average distances for the CBAs.

It is not surprising that the average distances between supplier billing

locations and beneficiary residences are greater in CBAs than in non-CBA MSAs and micro areas given the findings above that the CBAs are much larger areas and given that the majority of items furnished in the various areas are furnished by suppliers located in those areas. Regardless of the type of area, it makes sense that suppliers would locate their businesses in the places where most of the population resides (cities and towns). The means that the average distance travelled by the supplier will be weighted heavily in favor of the

shorter trips made from the location to the beneficiaries living in the immediate area. The supplier will also make much longer trips, but these trips would not have as great an impact on the average travel distance as the trips made to the population nucleus immediately surrounding the supplier location.

We also did this same analysis comparing average distances in CBAs versus non-CBAs broken out not based on whether the beneficiary resided in an MSA, micro area, or OCBSA, but broken out based on whether or not the

beneficiary resided in a super rural (SR) area based on the definition of super rural area used in the ambulance fee schedule rules in § 414.610(c)(5)(ii). Specifically, we used the April 2018 quarterly Zip Code to Carrier Locality File. When doing so, we found that out of all allowed services for DME items subject to the fee schedule adjustments,

9 percent of allowed services were furnished in SR areas. From 2015 to 2016, SR areas saw a 3 percent increase in allowed services. At the product category level, SR areas exhibit the same level of change in service volume as the rest of the nation. Without any data restrictions, CBAs tend to have greater average service distances than nonCBAs. For the restricted population, however, SR areas almost always show the greatest average distance. Lastly, we did not find any noticeable increase in service distance from 2015 to 2016 for any product category.

Table 37 shows the data for claims from all suppliers and Table 38 shows the data for the same restricted claims.

TABLE 37—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON CLAIMS FOR 2016

| Beneficiary area | Hospital beds | Oxygen |
|------------------|----------------|----------------|
| CBAs | 62 32 48 | 79 51 64 |

Table 38—Average Number of Miles Between Supplier and Beneficiary Based on Restricted Claims for 2016 ¹

| Beneficiary area | Hospital beds | Oxygen | All items |
|------------------|---------------|--------|-----------|
| CBAs | 25 | 21 | 27 |
| | 22 | 19 | 25 |
| | 36 | 35 | 41 |

¹ Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

We also did this same analysis comparing average distances in CBAs versus non-CBAs broken out not based on whether the beneficiary resided in an MSA, micro area, or OCBŠA, but broken out based on whether or not the beneficiary resided in a far and remote (FAR) area. We examined whether the beneficiary resided in a FAR area, as defined by the Office of Rural Health Policy in the Health Resources and Services Administration in a final notice published on May 5, 2014 in the Federal Register, titled "Methodology for Designation of Frontier and Remote Areas'' (79 FR 25599). FAR is a statistical delineation that defines frontier and remote areas based on remoteness and population sparseness. FAR areas are defined in relation to the

time it takes to travel by car to the edges of nearby Census defined Urban Areas. The Department of Agriculture maintains a list of ZIP codes that identify FAR areas in the U.S. Specifically, we used the 2010 Frontier and Remote Area Codes Data Files, last updated by the Department of Agriculture on April 15, 2015. There are four levels of FAR, as rural areas experience degrees of remoteness at higher or lower population levels that affect access to different types of goods and services.

We looked at whether the beneficiary resided in a FAR level 1 (FAR1) area: An area with a population of less than 50,000 people located 60 minutes or more from an area with a population of at least 50,000 people. Roughly 7

percent of items and services subject to competitive bidding nationally are furnished in these FAR1 areas.

We also compared average distances in CBAs versus non-CBAs broken out based on whether the beneficiary resided in a FAR level 3 (FAR3) area: An area with a population of less than 10,000 people located 30 minutes or more from an urban area of 10,000 to 24,999 people, 45 minutes or more from an urban area of 25,000 to 49,999 people, and 60 minutes or more from an urban area of 50,000 or more. Roughly 3 percent of items and services subject to competitive bidding nationally are furnished in these FAR3 areas.

Table 39 shows the data for claims from all suppliers and Table 40 shows the data for the same restricted claims.

Table 39—Average Number of Miles Between Supplier and Beneficiary Based on Claims for 2016

| Beneficiary area | Hospital beds | Oxygen |
|------------------|----------------------|----------------------|
| CBAs | 62 33 40 49 | 79 52 57 72 |

TABLE 40—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY BASED ON RESTRICTED CLAIMS FOR 2016 ¹

| Beneficiary area | Hospital beds | Oxygen | All items |
|------------------|---------------|--------|-----------|
| CBAs | 25 | 21 | 27 |

¹⁸ https://www.ers.usda.gov/data-products/frontier-and-remote-area-codes/.

TABLE 40—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY—Continued BASED ON RESTRICTED CLAIMS FOR 2016 1

| Beneficiary area | Hospital beds | Oxygen | All items |
|------------------|---------------|--------|-----------|
| Non-FAR Areas | 22 | 20 | 26 |
| | 29 | 30 | 37 |
| | 37 | 40 | 46 |

¹ Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

Average distances between suppliers and beneficiaries in areas falling under the current definition of rural areas at § 414.202 are not greater than the average distances in CBAs. When the restricted data for rural areas for non-CBAs is broken out by micro area and OCBSA, the distances are only slightly greater for OCBSAs than CBAs. However, when the restricted data for non-CBAs in general is broken out based on whether the non-CBA is a FAR3, Super Rural, or OCBSA, the distances between suppliers and beneficiaries are much greater than for the CBAs.

4. Cost Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the average costs associated with furnishing items and services in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. In our CY 2015 ESRD PPS proposed rule published in the **Federal** Register, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies;" (79 FR 40279), we noted that Congress previously mandated that the costs of furnishing DME in different geographic regions of the country be studied. Section 135 of the Social Security Act Amendments of 1994 (Pub. L. 103-432), required an examination of the geographic variations in DME supplier costs in order to determine whether the fee schedules are reasonably adjusted to account for any geographic differences. Jing Xing Health and Safety Resources, Inc. provided assistance to the Health Care Financing Administration, now CMS, in conducting this study. The project, titled "Durable Medical Equipment Supplier Product and Service Cost Study", was completed under Contract Number Health Care Financing Administration (HCFA) 500-95-0044 and submitted to the agency in June

1996.¹⁹ As part of the study, a Federal Advisory Panel was convened, a formal meeting with representatives of the DME industry was held, and a literature review was conducted. The general consensus among industry representatives and government agencies that participated in the study was that there is no conclusive evidence that urban and rural costs differed significantly or that the costs of furnishing DME items and services were higher in urban areas versus rural areas or vice versa.

Jing Xing Health and Safety Resources, Inc. summarized the findings from the study in a report titled "Final Report: Durable Medical Equipment Supplier Product and Service Cost Study", and stated that, "At one level, it is intuitively obvious that certain DME categories require a much larger service component than others. To illustrate, the service component in providing oxygen equipment is a larger proportion of costs than, for example, selling a walker or cane. The latter does not involve very much, if any, assembly, patient education, maintenance, etc." Additionally, "There was a general consensus among study participants that excluding the impact of volume purchasing the costs of acquiring DME items (that is, wholesale costs) are generally the same around the country with the possible exceptions of Alaska and Hawaii where shipping costs are greater. There was also general agreement that service costs do vary with the largest geographic variation resulting from labor costs. Limited tests using Medicare data provide support for the theory that geographic variation in the costs of providing DME is primarily caused by service components.'

In researching cost data for section 16008 of the Cures Act, we sought data that was national in scope, robust, and would allow us to access differences in costs of furnishing items and services in CBAs versus non-CBAs throughout the country. We also primarily sought data that was available at the county level, as

this allowed us to compare CBA counties to non-CBA counties. CBAs are currently comprised of whole counties, except when certain low population density areas are excluded from a county included in a CBA in accordance with section 1847(a)(3)(A) of the Act.

We examined four sources of cost data: (1) The Practice Expense Geographic Practice Cost Index (PE GPCI), (2) delivery driver wages from the Bureau of Labor Statistics (BLS), (3) real estate taxes from the U.S. Census Bureau's American Community Survey (ACS), and (4) gas and utility prices from the Consumer Price Index (CPI). Overall, we found that CBAs tended to have the highest costs out of the cost data that we examined, when compared to non-CBAs. We will now discuss the cost data sources we examined, and the methodology we used to analyze such cost data.

a. Cost Data Methodology

We first examined the PE GPCI. CMS first implemented the GPCIs as part of the Medicare Physician Fee Schedule (PFS) in 1992 (56 FR 59502). CMS must review and, if necessary, adjust the GPCIs at least every 3 years, as required by section 1848(e)(1)(C) of the Act. The most recent update occurred in 2017, in which a final rule was published on November 15, 2016 in the Federal Register, titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements" (81 FR 80170). The PE GPCIs are comprised of four component indices (employee wages; purchased services; office rent; and medical equipment, supplies and other miscellaneous expenses), and are designed to measure the relative cost difference in the mix of goods and services comprising practice expenses (not including malpractice expenses) among the 89 PFS fee schedule areas

 $^{^{19}\,}https://ia800903.us.archive.org/14/items/durablemedicaleq00kowa/durablemedicaleq00kowa.pdf.$

throughout the nation, as compared to the national average of these costs. The current 89 fee schedule areas are defined by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This configuration is used to calculate the GPCIs that are in turn used to calculate payments for physicians' services under the PFS (81 FR 80263).

The employee wage index measures several kinds of wages for clinical and administrative office staff. The current GPCI methodology relies on wage data from occupations representing 100 percent of total non-physician wages in the "offices of physicians: industry" from the BLS Occupational Employment Statistics (OES). This includes wages for "Medical secretaries," "Receptionists and information clerks," "Medical records and health information technicians," and other additional occupations.²⁰

The purchased services index includes BLS OES wages for occupations employed in industries from which physicians are likely to purchase services, which includes the cost of contracted services (for example, accounting, legal). This includes wages for "Commercial and industrial machinery and equipment repair and maintenance," "Services to buildings and dwellings," and other additional occupations.²⁰

The office rent index measures regional variation in the price of office rents using residential rent data from the U.S. Census Bureau's American Community Survey (ACS) on median gross rents for two-bedroom apartments. The ACS determines gross rent by adding up the following: Contract rent + utilities (electricity, gas, and water and sewer) + fuel (oil, coal, kerosene, wood, etc.). As such, we are using the PE GPCI as a proxy for commercial rent and utilities.

In a final rule published on November 15, 2016 in the **Federal Register**, titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes

Prevention Program Model; Medicare Shared Savings Program Requirements" final rule (81 FR 80170), we stated because Medicare is a national program, and section 1848(e)(1)(A) of the Act requires CMS to establish GPCIs to measure relative cost differences among localities compared to the national average, we believe it is important to use the best data that is available on a nationwide basis, that is regularly updated, and retains consistency areato-area, year-to-year (81 FR 80263). CMS discussed how there is currently no national data source available for physician office or other comparable commercial rents, which is why CMS uses county-level residential rent data from ACS as a proxy for the relative cost differences in commercial office rents. The ACS is administered by the U.S. Census Bureau, which is a leading source of national, robust, quality, publicly available data. A commercial data source for office rent that provided for adequate representation of urban and rural areas nationally would be preferable to a residential rent proxy. The GPCIs are not an absolute measure of practice costs, rather they are a measure of the relative cost differences for each of the three GPCI components. The U.S. Census Bureau is a federal agency that specializes in data collection, accuracy, and reliability, and we believe that where such a publicly available resource exists that can provide useful data to assess geographic cost differences in office rent, even though it is a proxy for the exact data we seek, we should utilize that available resource.

Therefore, given its national representation, reliability, high response rate and frequent updates, we believe the ACS residential rent data is the most appropriate data source available at this time for the purposes of analyzing rent and utilities. It is also worth noting that we examine utility prices from the CPI as another source of cost data, which is discussed further on in the preamble of this proposed rule.

The medical equipment, supplies and other miscellaneous expense cost index component of the PE GPCI measures practice expenses associated with a wide range of costs that include chemicals and rubber, to telephone and postage. The medical equipment, supplies, and miscellaneous expenses index holds that there is a national market for the items it measures such that there is not significant geographic variation in costs. Therefore, this index is given a value of 1.000 for each PFS fee schedule area. We discussed our reasoning behind this in the final rule published on November 15, 2004 in the

Federal Register, titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005" (69 FR 66235), stating "We were again unable to find any data sources that demonstrated price differences by geographic areas. As mentioned in previous updates, some price differences may exist, but these differences are more likely to be based on volume discounts rather than on geographic areas." Separately billable items such as DMEPOS are generally not included in this index, but this finding is consistent with the aforesaid findings from the Jing Xing Health and Safety Resources, Inc. study.

The PE GPCIs are calculated at the fee schedule area level after aggregating the county-level component indexes. The PE GPCI county level data are for informational purposes only so that interested parties can have a better understanding of the data that underpin their fee schedule area GPCI values. In order to compare CBAs and non-CBAs, we used CY 2017 PE GPCI county data (CY 2017 PFS final rule (81 FR 80170)) found in the GPCI public use files.21 This allowed us to then map each county in this dataset to either a CBA, or non-CBA by MSA, micro area, or OCBSA county, and to then see its corresponding PE GPCI. The counties and county equivalent names listed in this file are from the 2010 U.S. Census.

When mapping counties to CBAs, we selected all counties that were included in Round 2 Recompete or Round 1 2017. We then used OMB Bulletin No. 15-01 as the source for mapping the remaining counties to either non-CBA by MSAs, micro areas, or OCBSAs.²² After doing this, we grouped all contiguous counties of the U.S. with the same delineation and BEA Region together. We grouped any non-contiguous counties of the U.S. with the same delineation together. We then calculated the weighted average of each delineation's PE GPCI value using U.S. Census 2010 total resident population numbers for each county. For this PE GPCI analysis, we included all 50 states and the District of Columbia.

Although counties in Puerto Rico and the Virgin Islands have a PE GPCI value, each is assigned the GPCI national average of 1.0. For the Virgin Islands, because county-level wage and rent data are not available, and insufficient malpractice premium data are available, CMS has set the PE GPCI values for the

²⁰ Proposed Revisions to the Sixth Update of the Geographic Practice Cost Index. https:// www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CMS_ 1524 P CY2012 PFS NPRM GPCI Revisions.pdf.

²¹ https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1654-F.html.

²² https://www.whitehouse.gov/sites/ whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.

Virgin Islands fee schedule area at the national average of 1.0 (81 FR 80269). In an effort to provide greater consistency in the calculation of GPCIs given the lack of comprehensive data regarding the validity of applying the proxy data used in the states in accurately accounting for variability of costs for these island territories, we discussed in a final rule published on November 15, 2016 in the Federal Register, titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements" final rule (81 FR 80170) that we would treat the Caribbean Island territories (the Virgin Islands and Puerto Rico) in a consistent manner. We thus finalized a proposal to do so by assigning the national average of 1.0 to each GPCI index for both Puerto Rico and the Virgin Islands. Thus, in calculating weighted average PE GPCIs for noncontiguous areas, we only incorporated PE GPCIs from Hawaii and Alaska.

Because stakeholders on the March 23, 2017 stakeholder call indicated that deliveries make up a significant part of the costs when furnishing items and services, we examined delivery driver wages as the next source of cost data. The BLS OES provides delivery driver wage data in the "53-0000 Transportation and Material Moving Occupations" occupation group. Specifically, we used the "53-3033 Light Truck or Delivery Services Drivers" individual occupation wage index, which is underneath the "53-0000 Transportation and Material Moving Occupations" occupation group.

We used the median hourly wage from the "53–3033 Light Truck or Delivery Services Drivers" individual occupation wage index as the source of this delivery driver wage data. We used median hourly wage values from the May 2016 Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates.²³

For this analysis, we used a similar methodology that we used for the aforesaid PE GPCI analysis. We mapped each county to two areas: Its corresponding delineation (CBA, non-CBA MSA, non-CBA micro area, or non-CBA OCBSA), and its BEA Region. We then mapped counties to their

corresponding median hourly wage by using the May 2016 Metropolitan and Nonmetropolitan Area Definitions provided by the BLS.24 In cases where BLS did not have a median hourly delivery driver wage for a particular county, we calculated and then assigned such counties the median hourly delivery driver wage for that county's state (this was the case for the following counties: Bradley County, Tennessee (TN); Polk County, TN; Los Alamos County, New Mexico; Champaign County, Illinois (IL); Piatt County, IL; Ford County, IL; Kankakee County, IL). In order to come up with an hourly wage for each BEA Region and delineation, we calculated the weighted average of the median hourly wages for the counties within each area, basing the weighted average off of each county's U.S. Census total resident 2010 population numbers.

For New England states, the BLS assigns wages to New England city and town areas (NECTAs) instead of metropolitan and non-metropolitan areas that adhere to county boundaries, which the BLS does for every other area outside of New England. An issue with assigning wages to NECTAs is that there is not a one-to-one mapping of NECTAs to counties, as the collection of townships in a NECTA may not completely cover a county. This results in counties being represented in multiple NECTAs. To address this issue, we mapped NECTAs to New England counties by using the U.S. Census Bureau's "NECTAs, NECTA divisions, and combined NECTAs" file that is based on OMB Bulletin No. 15-01 delineations.²⁵ If a New England county had more than one NECTA, we calculated the weighted average of each of its NECTAs' median hourly wages. We used total population estimates from the 2016 ACS for the population weighting (U.S. Census Bureau, 2012-2016 ACS 5-Year Estimates).

OMB set the standards for NECTAs in the notice published on June 28, 2010 in the Federal Register, titled "2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas" (75 FR 37245). Based upon these standards, 10 counties in New England did not have any towns or cities that qualified as NECTAs (Aroostook County, Maine (ME); Caledonia County, Vermont (VT); Carroll County, New Hampshire; Essex County, VT; Franklin County, ME; Knox County, ME; Nantucket County, Massachusetts; Orleans County, VT;

Washington County, ME; and Windham County, (VT). We assigned delivery driver wages to these 10 counties based upon which area each of these counties' seat were located in the May 2016 Metropolitan and Nonmetropolitan Area Definitions provided by BLS.²⁶

We also used ACS data to examine real estate taxes. We analyzed 2016 data from the survey titled "Mortgage Status by Median Real Estate Taxes Paid (Dollars) Universe: Owner-occupied housing units".27 In this survey, ACS provides a median real estate tax for each U.S. county, thus allowing us to use a similar methodology that we used for the PE GCPIs and delivery driver wages. In order to come up with a real estate tax value for each BEA Region and delineation, we calculated the weighted average of the median real estate tax values for the counties within each area, basing the weighted average off of each county's U.S. Census total resident 2010 population numbers. It is worth noting that the ACS measures real estate taxes paid on housing units, not business units. However, similar to our reasoning above for using residential rent data provided by the ACS as a proxy for commercial rent, we believe the ACS is a valuable tool in measuring geographic differences in cost, and are also using real estate taxes on housing units as a proxy to measure taxes paid on business units.

In order to further examine costs, we also analyzed CPI data for gas and utility prices. For each month in 2016, BLS released a CPI detailed report with monthly prices for various data included in the CPI.28 In order to analyze gas prices, we compiled the CPI detailed report for every month in 2016, and calculated the annual average for the values in the "Gasoline All Types" index of "Table P3: Average prices for gasoline, U.S. city average and selected areas" of the CPI detailed report. In order to analyze utility prices, we compiled the CPI detailed report for every month in 2016, and calculated the annual average for the values in "Table P2: Average residential unit prices and consumption ranges for utility (piped) gas and electricity for U.S. city average and selected areas". Specifically, we looked at the "Average price per therm of utility (piped) gas" and the "Average price per KWH of electricity" index in the CPI report. As discussed earlier in the preamble of this proposed rule, the Office Rent Index of the PE GPCI

²³ https://www.bls.gov/oes/tables.htm.

²⁴ https://www.bls.gov/oes/current/msa_def.htm.
25 https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files/time

 $^{^{26}\,\}mathrm{NACo}$ Analysis of U.S. Census Bureau, NACo Research, 2013.

 $^{^{27}}$ U.S. Census Bureau, 2012–2016 American Community Survey 5-Year Estimates.

²⁸ https://www.bls.gov/cpi/cpi_dr.htm.

already includes utilities in its calculation, based on ACS residential rent data. Nevertheless, we examined an additional source of utility prices, in order to further examine any potential price trends.

BLS separates prices in these tables based upon the following size classes: A, B/C, and D. Size A represents metropolitan areas with a population of over 1,500,000, size B/C represents midsized and small metropolitan areas (population of 50,000 to 1,500,000), and size D represents nonmetropolitan urban areas.²⁹

An issue with CPI size classes is that the CPI data cannot directly map to every county and BEA Region in the U.S., unlike the previously discussed cost data. This is because the CPI data is only available at the national level, for a select number of metropolitan areas, and for the four U.S. Census Bureau Regions.

However, the CPI sampled a total of 87 Primary Sampling Units (PSUs) for the 2016 CPI, which are the smallest geographic areas in which pricing is done for the CPI. Appendix 4 in Chapter 17 of the BLS Handbook of Methods lists the 87 PSUs sampled in the 2016 CPI.³⁰ Appendix 4 also lists the counties in these PSUs that the CPI sampled, which totaled 425 counties and included counties in the contiguous and non-contiguous U.S.

We found that CBA counties made up the majority of size class A and B/C. while non-CBA micro and OCBSA counties made up the majority of size class D. The exact number can be found in Table 41, and the exact percentages can be found in Table 42. In order to identify the delineation of these counties and to be consistent with our previous cost data analyses, we used the same reference materials that we used for our previous cost data analyses: county and county equivalent names from the 2010 U.S. Census, and county and county equivalent delineations from OMB Bulletin No. 15-01.

It is worth noting that although the CPI data is from 2016, the 2016 CPI bases the counties and county equivalents and their size classes off of the 1990 decennial Census and its Metropolitan Areas off of OMB Bulletin No. 93–05.³¹ One implication of this is that counties and county equivalents sampled in the 2016 CPI may have changed size classes based upon their population numbers in the 2010 Census, and their Metropolitan Area status in

OMB Bulletin No. 15-01. Further, CBSAs, micro areas, and OCBSAs were not a concept at the time in OMB Bulletin No. 93-05. Additionally, the counties and county equivalents that the CPI sampled were based off of the 1990 U.S. Census, meaning that the CPI data would not reflect any substantial changes to counties and county equivalent entities after 1990, as indicated by the U.S. Census Bureau.³² However, most of the county and county equivalent names that the CPI sampled remained the same or were similar to those in the 2010 U.S. Census, allowing us to map the counties and county equivalents listed in Appendix 4 of Chapter 17 of the BLS Handbook of Methods to those in the 2010 U.S. Census. We also believe that this CPI data is a valuable tool in examining price trends for gas and utilities amongst differently sized areas with varying levels of urbanization. Further, because we are able to know which counties the CPI sampled, we are able to know which size classes have CBA and non-CBA counties, thus allowing us to compare costs between CBAs and non-CBAs, making it useful for our data purposes in fulfilling section 16008 of the Cures Act.

Table 41—Number of Counties Sampled in 2016 CPI

| Delineation | Size A | Size B/C | Size D | Total number counties |
|-----------------------|---------------------|--------------------|------------------|-----------------------|
| CBA | 235 26 5 1 | 86 46 8 0 | 1 3 8 6 | 322 75 21 7 |
| Total number Counties | 267 | 140 | 18 | 425 |

Table 42—County Delineation Percentages for 2016 CPI

| Delineation | Size A | Size B/C | Size D |
|-------------|--------|----------|--------|
| | % | % | % |
| CBA | 88.01 | 61.43 | 5.56 |
| | 9.74 | 32.86 | 16.67 |
| | 1.87 | 5.71 | 44.44 |
| | 0.37 | 0.00 | 33.33 |
| Total | 100.00 | 100.00 | 100.00 |

b. Cost Data Results

We found that, on average, CBAs had higher costs than non-CBAs, for most of the cost data that we examined. For instance, CBAs had the highest average PE GPCI in every BEA Region, when compared to the non-CBAs in each BEA Region. CBAs had the highest average driver wage in all but one BEA Region (Rocky Mountain), when compared to the non-CBAs in each Region. CBAs also had the highest average real estate tax in every BEA Region, when compared to the non-CBAs in each BEA Region.

Typically, the ranking from highest to lowest cost delineation in each BEA Region was the following: (1) CBA, (2) non-CBA MSA, (3) non-CBA micro, and (4) non-CBA OCBSA. Thus, the more urbanized areas tended to have higher costs than the less urbanized areas.

²⁹ https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.

³⁰ BLS Handbook of Methods. Chapter 17. The Consumer Price Index. (Updated 06/2015).

³¹ https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.

³² https://www.census.gov/geo/reference/county-changes.html.

Additionally, we found that BEA Regions have different costs. We arranged the 8 BEA Regions into two cost tiers, for each of the cost data that we examined. The top tier included BEA Regions where costs were, on average, the highest. The bottom tier included BEA Regions where costs were, on average, the lowest. To be in the top tier, a BEA Region had to have a value that was in the top 50 percent of all 8 BEA Region values. To be in the bottom tier, a BEA Region had to have a value that was in the bottom 50 percent of all 8 BEA Region values. Overall, the Far West, Mideast, and New England Regions tended to be in the top cost tier for most of the cost data sources that we examined. The Far West Region was in the top cost tier most often, indicating that its costs are amongst the highest out of the 8 BEA Regions.

The Far West, New England, Mideast, and Rocky Mountain BEA Regions were in the top tier of average PE GPCI values in the 8 BEA Regions. For instance, when looking at the average PE GPCI value for each of the 8 BEA Regions, these 4 BEA Regions' average PE GPCI values were in the top 50 percent for every delineation. The bottom tier included the Great Lakes, Southwest, Plains, and Southeast BEA Regions. They were all in the bottom 50 percent of average PE GPCI values, for every delineation.

When looking at the average delivery driver wage for each of the 8 BEA Regions, the Plains and Far West Regions' average driver wage were in the top 50 percent for every delineation. New England, Mideast, and Rocky Mountain were also a part of this top tier, yet alternated in and out of the top 50 percent, depending on which delineation we examined. The bottom tier for delivery driver wages included the Great Lakes, Southwest, and Southeast BEA Regions.

For real estate taxes, the New England and Mideast BEA Regions had significantly higher real estate taxes, on average, than every other BEA Region, for each delineation. The BEA Regions of New England, Mideast, Far West, and the Great Lakes were in the top 50 percent of real estate taxes for every delineation. The BEA Regions of Southwest, Plains, Southeast, and Rocky Mountain were in the bottom 50 percent of real estate taxes for every delineation.

It is worth noting that we did not include non-contiguous areas in the average values for the 8 BEA Regions, and instead counted non-contiguous areas as their own type of area. In doing so, we found that the average PE GPCI for non-contiguous delineations (in Alaska and Hawaii) were higher than every other delineation in the 8 BEA Regions. Additionally, the average driver wage for non-contiguous

delineations (in Alaska and Hawaii), were higher than every other delineation in the 8 BEA Regions, except for non-contiguous micro areas, which were only lower than driver wages in the micro areas of the Rocky Mountain BEA Region. When we included driver wages from Puerto Rico in the non-contiguous average driver wage calculation (along with Alaska and Hawaii), the Puerto Rico driver wages lowered the average non-contiguous driver wages so that OCBSAs were then the only non-contiguous delineation with a higher value than delineations in the 8 BEA Regions.

Lastly, there were certain non-CBA counties around the country that had relatively high driver wages—driver wages that were higher than that of CBA counties. These counties primarily were in the Plains, Rocky Mountain, and Far West BEA Regions. Many of these non-CBA counties with higher driver wages were either OCBSAs or micro areas. However, many other OCBSA or micro counties elsewhere in the country had relatively low driver wages. It is also worth noting that these very same counties that had higher driver wages had relatively low PE GPCI values and real estate taxes.

Table 43 shows the summary of these cost data results.

TABLE 43—AVERAGE COSTS BY BEA REGION

| BEA region | Delineation | Delineation PE GPCI | | Annual residential real estate tax | |
|----------------|-------------|---------------------|---------|---|--|
| Far West | CBA | 1.14 | \$15.79 | \$3,463.59 | |
| Far West | MSA | 1.03 | 15.11 | 2,413.43 | |
| Far West | Micro | 0.96 | 15.04 | 1,778.87 | |
| Far West | OCBSA | 0.96 | 15.06 | 1,663.85 | |
| Great Lakes | CBA | 0.97 | 14.77 | 3,338.46 | |
| Great Lakes | MSA | 0.92 | 14.08 | 2,322.51 | |
| Great Lakes | Micro | 0.87 | 13.19 | 1,629.62 | |
| Great Lakes | OCBSA | 0.86 | 12.85 | 1,491.14 | |
| Mideast | CBA | 1.11 | 15.92 | 5,245.05 | |
| Mideast | MSA | 0.96 | 13.92 | 3,132.32 | |
| Mideast | Micro | 0.89 | 12.97 | 2,102.79 | |
| Mideast | OCBSA | 0.89 | 13.46 | 2,208.62 | |
| New England | CBA | 1.10 | 16.49 | 4,725.59 | |
| New England | MSA | 1.02 | 14.88 | 3,739.11 | |
| New England | Micro | 1.00 | 14.02 | 4,065.67 | |
| New England | OCBSA | 0.93 | 13.17 | 2,317.18 | |
| Plains | CBA | 0.98 | 16.20 | 2,408.32 | |
| Plains | MSA | 0.90 | 14.45 | 2,049.21 | |
| Plains | Micro | 0.87 | 13.34 | 1,489.76 | |
| Plains | OCBSA | 0.84 | 13.52 | 1,160.55 | |
| Rocky Mountain | CBA | 1.00 | 15.28 | 1,658.02 | |
| Rocky Mountain | MSA | 0.93 | 14.60 | 1,506.69 | |
| Rocky Mountain | Micro | 0.93 | 16.09 | 1,428.58 | |
| Rocky Mountain | OCBSA | 0.88 | 15.64 | 1,047.09 | |
| Southeast | CBA | 0.97 | 14.47 | 1,821.26 | |
| Southeast | MSA | 0.90 | 13.19 | 1,094.17 | |
| Southeast | Micro | 0.84 | 12.38 | 787.18 | |
| Southeast | OCBSA | 0.83 | 12.12 | 624.88 | |
| Southwest | CBA | 0.97 | 14.38 | 2,643.70 | |

TABLE 43—AVERAGE COSTS BY BEA REGION—Continued

| BEA region | Delineation | PE GPCI | Average median driver wage per hour | Annual residential real estate tax |
|------------|-------------|---------|--|---|
| Southwest | MSA | 0.91 | 13.42 | 1,698.48 |
| | Micro | 0.87 | 12.96 | 1,054.82 |
| | OCBSA | 0.85 | 12.66 | 915.76 |

Tables 44 through 46 summarize the data at the national contiguous level and for non-contiguous areas.

TABLE 44—AVERAGE COSTS FOR THE CONTIGUOUS U.S.

| Delineation | PE GPCI | Average median driver wage per hour | Annual residential real estate tax |
|-------------|--------------|---|---|
| CBA | 1.04 | \$15.24 | \$3,301.60 |
| MSA | 0.93 0.88 | 13.95 13.23 | 1,943.28 1,415.56 |
| OCBSA | 0.85 | 12.95 | 1,083.05 |

TABLE 45—AVERAGE COSTS FOR THE NON-CONTIGUOUS U.S. (ALASKA, HAWAII)

| Delineation | PE GPCI | Average median driver wage per hour | Annual residential real estate tax |
|---------------------------------------|---------|---|---|
| CBA (Honolulu, HI) MSA Micro OCBSA | 1.17 | \$15.35 | \$1,710.00 |
| | 1.11 | 19.12 | 2,863.27 |
| | 1.05 | 15.42 | 1,230.27 |
| | 1.09 | 21.65 | 1,600.30 |

TABLE 46—AVERAGE COSTS FOR THE NON-CONTIGUOUS U.S. (ALASKA, HAWAII, AND PUERTO RICO)

| Delineation | PE GPCI | Average median driver wage per hour | Annual residential real estate tax |
|--------------------|---------|---|---|
| CBA (Honolulu, HI) | 1.17 | \$15.35 | \$1,710.00 |
| | 1.02 | 10.39 | 846.20 |
| | 1.04 | 13.33 | 958.94 |
| | 1.08 | 19.98 | 1,429.99 |

As discussed earlier, BLS separates certain CPI data based upon the following size classes: A, B/C, and D. Size A represents metropolitan areas with a population of over 1,500,000 people, size B/C represents mid-sized and small metropolitan areas (population of 50,000 to 1,500,000), and size D represents nonmetropolitan urban areas.³³ For the gas and utility CPI data in Tables 50, 51, and 52, the typical ranking was the following from highest to lowest price: (1) size class A, (2) size

33 https://www.bls.gov/opub/mlr/1996/12/art2full.pdf.

class B/C, and (3) size class D. This is thus similar to our other cost data summarized in Tables 43, 44, 45, and 46, in that the more populated urban areas (size class A and B/C) tended to have higher average costs than the less populated urban areas (size class D). Additionally, CPI size classes with more CBA counties (size class A and B/C) tended to have higher average costs than size classes with more non-CBA counties (size class D). Thus, we conclude based off this CPI data in Tables 47, 48, and 49, that CBAs generally have higher gas prices and

residential utility prices, on average, than non-CBAs.

TABLE 47—AVERAGE PRICES FOR GASOLINE, U.S. CITY AVERAGE AND SELECTED AREAS

[Per Gallon]
Gasoline all Types

| Urban area size class | National average 2016 |
|-----------------------|-----------------------------|
| A | \$2.296 2.102 2.128 |

TABLE 48—AVERAGE RESIDENTIAL UNIT PRICES AND CONSUMPTION RANGES FOR UTILITY (PIPED) GAS AND ELECTRICITY FOR U.S. CITY AVERAGE AND SELECTED AREAS

Average Price per KWH of Electricity

| Urban area size class | National average 2016 |
|-----------------------|-----------------------------|
| A | \$0.150 0.125 0.117 |

TABLE 49—AVERAGE RESIDENTIAL UNIT PRICES AND CONSUMPTION RANGES FOR UTILITY (PIPED) GAS AND ELECTRICITY FOR U.S. CITY AVERAGE AND SELECTED AREAS

Average Price per Therm of Utility (Piped) Gas

| Urban area size class | National average 2016 |
|-----------------------|-----------------------------|
| A | \$0.949 0.894 0.829 |

5. The Average Volume of Items and Services Furnished by Suppliers in the Area Analysis

Section 16008 of the Cures Act mandates that we take into account a

comparison of the average volume of items and services furnished by suppliers in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1, 2019, based on information from the CBP. We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items to the various areas is higher in CBAs than non-CBAs. As indicated in Table 50, the difference in volume is more pronounced as the size of the area in terms of population declines.

TABLE 50—ALLOWED SERVICES PER SUPPLIER IN 2015 AND 2016 FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS

| Areas | Allowed services (2015) | Suppliers serving area (2015) | Allowed services per supplier (2015) | Allowed services (2016) | Suppliers serving area (2016) | Allowed services per supplier (2016) |
|------------------|-------------------------------------|-------------------------------------|---|--------------------------------------|-------------------------------------|---|
| | | CPAP & RA | Ds | | | |
| CBAs | 9,140,617 4,780,160 4,318,843 | 4,091 4,977 5,519 | 2,234 960 783 | 10,634,486 5,474,533 4,928,348 | 4,064 4,918 5,372 | 2,617 1,113 917 |
| | | Oxygen | | | | |
| CBAs | 6,406,412 3,766,780 4,521,374 | 4,667 4,883 5,325 | 1,373 771 849 | 6,265,856 3,662,808 4,420,783 | 4,289 4,548 5,036 | 1,461 805 878 |
| | | Nebulizer | s | | | |
| CBAs | 2,088,109 1,132,972 1,372,641 | 7,643 6,167 7,002 | 273 184 196 | 1,769,830 1,032,926 1,267,774 | 6,392 5,742 6,509 | 277 180 195 |
| | | Standard Whee | Ichairs | | | |
| CBAs | 1,589,682 652,588 600,098 | 3,428 4,687 5,441 | 464 139 110 | 1,624,569 658,504 609,432 | 3,419 4,451 5,190 | 475 148 117 |
| | | WC Accesso | ries | | | |
| CBAs | 1,339,631 431,487 334,264 | 2,903 3,505 4,093 | 461 123 82 | 1,388,992 456,145 355,364 | 2,909 3,388 3,938 | 477 135 90 |
| | | Hospital Be | eds | | | |
| CBAs | 791,371 314,095 332,047 | 2,814 3,870 4,460 | 281 81 74 | 781,486 310,312 331,278 | 2,707 3,647 4,212 | 289 85 79 |
| | | Infusion Pur | nps | | | |
| CBAs | 741,236 305,067 268,204 | 1,320 1,415 1,589 | 562 216 169 | 641,192 258,168 224,845 | 1,329 1,388 1,498 | 482 186 150 |
| | | Walkers | | | | |
| CBAsNon-CBA MSAs | 466,112 255,487 | 3,558 5,367 | 131 48 | 465,134 248,570 | 3,722 5,138 | 125 48 |

TABLE 50—ALLOWED SERVICES PER SUPPLIER IN 2015 AND 2016 FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS—Continued

| Areas | Allowed services (2015) | Suppliers serving area (2015) | Allowed services per supplier (2015) | Allowed services (2016) | Suppliers serving area (2016) | Allowed services per supplier (2016) |
|---------------|-------------------------------|-------------------------------------|---|-------------------------------|-------------------------------------|---|
| Non-CBA Rural | 230,651 | 6,488 | 36 | 227,668 | 6,094 | 37 |
| | | Commode Cl | nairs | | | |
| CBAs | 191,538 69,232 63,932 | 3,656 3,193 3,845 | 52 22 17 | 177,339 67,323 61,175 | 3,010 2,838 3,483 | 59 24 18 |
| | | NPWT | | | | |
| CBAs | 182,939 86,421 76,583 | 1,413 1,371 1,565 | 129 63 49 | 182,375 87,326 79,939 | 1,380 1,347 1,532 | 132 65 52 |
| | | Patient Lif | ts | | | |
| CBAs | 161,975 55,504 52,133 | 2,450 2,262 2,724 | 66 25 19 | 156,168 53,969 50,405 | 2,223 2,124 2,532 | 70 25 20 |
| | | Support Surf | aces | | | |
| CBAs | 131,756 51,675 47,302 | 1,859 2,186 2,665 | 71 24 18 | 128,033 50,267 47,402 | 1,725 2,113 2,519 | 74 24 19 |
| | | TENS | | | | |
| CBAs | 119,135 55,563 55,020 | 1,164 780 867 | 102 71 63 | 53,695 28,878 28,207 | 1,031 697 791 | 52 41 36 |
| | | Seat Lifts | 3 | | | |
| CBAs | 5,925 3,774 6,032 | 1,057 927 1,326 | 6 4 5 | 3,026 2,652 4,439 | 715 746 1,151 | 4 4 4 |
| | | Complex Whee | Ichairs | | | |
| CBAs | 1,059 581 420 | 209 176 140 | 5 3 3 | 1,295 618 544 | 236 199 171 | 5 3 3 |

Notes: Complex wheelchairs include Group 2 complex rehabilitative power wheelchair bases.

One factor to consider is that as a supplier's volume increases, the overall costs of furnishing those items also increases due to the need to purchase more delivery vehicles, hire additional employees, expand warehouse and office space, purchase additional office equipment, additional use of gas and other utilities, etc.

Past stakeholder input and studies suggest that delivery costs and wages affect a suppliers' overall costs more than equipment acquisition costs and volume discounts. In 2006, Morrison Informatics, Inc. conducted a study for the American Association for Homecare titled "A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy", which used a survey of 74 oxygen suppliers to determine which factors are

more important in influencing oxygen suppliers' cost of furnishing oxygen and oxygen equipment. The study concluded that equipment acquisition only accounted for 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. This study concluded that services such as preparing and delivering equipment, driving to the home to repair and maintain equipment, training and educating patients, obtaining required medical necessity documentation, customer service, and operating and overhead costs accounted for 72 percent of overall costs. Our data indicates that delivery, wages, gasoline, utilities, office rental, and other overhead costs are lower in non-CBAs than in CBAs, and

the findings of the Morrison study indicate that these costs represent a majority of the supplier's overall cost.³⁴

Table 2 from the Morrison study provided a breakdown of an oxygen supplier's monthly cost per patient of \$201.20 into seven components: One for equipment cost; four for labor for various tasks; one for delivery; and one for overhead, including rent and other facility costs. Table 51 represents that table from the study.

³⁴ Morrison Informatics, Inc., A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy (Mechanicsburg, Pa.: June 27, 2006).

TABLE 51—2006 OXYGEN SUPPLIER Cost SURVEY BY **MORRISON** INFORMATICS, INC

| Cost component | Average cost per- patient per-month | |
|--|--|-------------------------|
| 1. SYSTEM ACQUISITION 1 2. INTAKE AND CUS- | \$55.81 | 7. C |
| TOMER SERVICE ² | 12.66 | 8. T B |
| TENANCE 3 | 25.24 | stat serv |
| NANCE 4 5. PATIENT ASSESSMENT, TRAINING, EDUCATION | 6.10 | and 2 pati |
| AND MONITORING 5 6. DELIVERY ASSOCIATED WITH PREPARATION, RETURN, DISPOSABLES, AND SCHEDULED MAIN- | 17.54 | serverie dati new |
| TENANCE 6 | 42.26 | |

TABLE 51—2006 OXYGEN SUPPLIER SURVEY Cost BY MORRISON INFORMATICS, INC—Continued

| 8. TOTAL DIRECT COST | Cost component | Average cost per- patient per-month |
|----------------------|--|--|
| | ERATING AND OVER- HEAD ⁷ | 41.59 |
| BEFORE TAXES 20 | BEFORE TAXES | 201.20 |

The amount includes acquisition costs for tionary, portable and backup units, conving devices, ancillary equipment and acsories, and oxygen system contents (liquid d gaseous oxygen).

The amount includes labor associated with tient intake functions, ongoing customer vice (patient inquiries, scheduling of delives/maintenance/clinical visits, accommoing patient travel plans), and initial and rewal prescription processing.

³The amount includes labor associated with equipment preparation (testing, cleaning, and repair), equipment set-up and maintenance upon return, initial patient instruction, cost of disposable and maintenance supplies, and labor costs associated with scheduled preventive equipment maintenance.

⁴The amount includes labor and vehicle costs associated with unscheduled equipment

repair and maintenance.

⁵ The amount includes labor and travel costs associated with clinical visits by respiratory care practitioner, in-home patient assessments (including home environment safety assessment and oxygen therapy plan of care), training, education and compliance monitoring.

6 The amount includes delivery costs associ-

ated with oxygen fills (liquid and gaseous oxygen), preparation, return, disposables and scheduled maintenance.

⁷The amount includes rent and other facility costs, administration, insurance, legal, regulatory compliance, MIS systems/controls, communications systems, employee training, accreditation, supplies, billing and compliance functions

Table 52 combines the monthly costs from Table 2 of the Morrison study into the major components of a DME supplier's costs: Equipment cost; labor cost; delivery cost; and overhead.

TABLE 52—DOLLAR COST BREAKOUT FOR DME SUPPLIER OF OXYGEN AND OXYGEN EQUIPMENT

| Monthly average cost per beneficiary | Component | Percentage of total cost (percent) |
|--------------------------------------|----------------------|--|
| \$55.81 | Oxygen Equipment | 28 |
| 61.54 | Combined Labor Costs | 30 |
| 42.26 | Delivery | 21 |
| 41.59 | Overhead | 21 |
| 201.20 | Total Cost Per Month | 100 |

The average volume of oxygen equipment furnished by suppliers in CBAs is greater than the average volume of oxygen equipment furnished by suppliers in non-CBAs, particularly rural areas, as shown previously in Table 50. But volume discounts associated with bulk purchasing of oxygen equipment, or the lack thereof, would only impact 28 percent of the suppliers' total cost per month according to the Morrison study. The Morrison study concludes that labor, delivery, and overhead costs combined account for far more of the oxygen supplier's overall cost (72 percent) than the cost of the oxygen equipment (28 percent). Even if the supplier received a 25 percent volume discount on the price of the equipment from the manufacturer, reducing its monthly cost for the equipment from \$55.81 to \$41.86, this savings would be more than cancelled out if the supplier's labor, delivery, and overhead costs are just 10 percent higher than the supplier in the area with lower costs and lower volume. Also, as a supplier increases their volume, the costs associated with labor,

delivery, and overhead also increase proportionally. The conclusion drawn from the Morrison study is that although the average volume of oxygen and oxygen equipment furnished by suppliers in the CBAs may be higher than the average volume of oxygen and oxygen equipment furnished by suppliers in the non-CBA areas, this factor alone does not mean that the overall costs of furnishing oxygen and oxygen equipment in the CBAs is lower than the overall costs of furnishing oxygen and oxygen equipment in the non-CBAs. Our data indicates that the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in CBAs are higher than the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in non-CBAs, and the Morrison study concludes that these costs make up 72 percent of the oxygen supplier's overall costs.

6. Number of Suppliers Analysis

Section 16008 of the Cures Act mandates that we take into account a comparison of the number of suppliers

in CBAs and non-CBAs in making adjustments to fee schedule amounts for items furnished on or after January 1. 2019, based on information from the CBP. We examined data regarding the number of suppliers serving the various CBAs and did not find any correlation between number of suppliers and SPA or maximum winning bid amount. We are not certain how much this factor might affect costs in terms of competition for business or serving areas with a limited number of suppliers, but it does not appear to have been a factor under the competitive bidding program in terms of bids submitted in the various CBAs.

Data for number of suppliers per area and product category did not change significantly in 2016 from levels in 2015. There was at least a double digit number of suppliers serving non-CBAs in almost every MSA, micro area or other rural counties for items subject to the fee schedule reductions. The number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, while volume per supplier increased, suggesting a consolidation in

the number of locations serving the non-CBAs

We believe that one of the most critical items subject to the fee schedule adjustments in terms of beneficiary access is oxygen and oxygen equipment. If access to oxygen and oxygen equipment is denied to a beneficiary who needs oxygen, this can have serious health implications. Oxygen and oxygen equipment is also an item that must be delivered to the beneficiary and set up and used properly in the home for safety reasons. Access to oxygen and oxygen equipment in remote areas is critical and this has been stressed by stakeholders. To determine if there were pockets of the country where access to oxygen and oxygen equipment was in jeopardy, we looked at data showing how many non-CBA counties are being served by only one oxygen supplier. This data shows that these instances are extremely rare (35 counties out of about 2,700 counties in 2016 and 2017) and that the suppliers serving these counties are all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time. Of the 35 counties, 28 have only one beneficiary using oxygen, so only one supplier could serve these counties at one time, meaning that there may be other suppliers able to serve these areas as well if there were more beneficiaries using oxygen in these areas. Also of note, 28 of these counties are from Puerto Rico (25), Alaska (2), or the Virgin Islands (1), and the suppliers for these non-contiguous areas are all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time and are continuing to serve these areas.

7. Fee Schedule Adjustment Impact Monitoring Data

Regarding adverse beneficiary health outcomes, we have been monitoring claims data from non-CBAs and it does not show any observable trends indicating an increase in adverse health outcomes such as mortality, hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, or emergency room visits in 2016, 2017, or 2018 compared to 2015 in the non-CBAs, overall. In addition, we have been monitoring data on the rate of assignment in non-CBAs and it remains high (over 99 percent) in most areas, which reflects when suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME. We are, however, soliciting comments on ways to improve our fee schedule adjustment impact monitoring data.

8. Summary of Our Findings

A brief summary of our general findings gathered in accordance with section 16008 of the Cures Act are as follows:

Highest Winning Bid

Highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others).

Stakeholder Input

Stakeholders, most of which were suppliers, stated that the fully adjusted fee schedule amounts are not sufficient to cover supplier costs for furnishing items and services in non-CBAs. Stakeholders also stated that the number of suppliers furnishing items in these areas continues to decline, the average travel distance and cost for suppliers serving rural areas are greater than the average travel distance and cost for suppliers serving CBAs, and that the average volume of services furnished by suppliers when serving non-CBAs are lower than the average volume of services furnished by suppliers when serving CBAs. Many commenters also stated that the adjusted fee schedule amounts have caused or will cause beneficiary access issues, and that beneficiaries are going without items and that this is causing adverse health outcomes. Several commenters stated that they have reduced the size of their service area due to the level of reimbursement that they are receiving. Five commenters suggested that the adjusted fee schedule amounts be based on maximum winning bids in CBAs.

Distance

From our analysis presented in this rule, the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as FAR, OCBSAs, and super rural areas, suppliers generally must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs.

Costs

Costs, on average, are higher in CBAs than they are in the non-CBAs, for most of the cost data that we examined and presented in this proposed rule.

Volume

Overall, suppliers in CBAs have significantly more volume than suppliers in either non-CBA MSAs,

micro areas, or OCBSAs, based on claims data we examined and the analysis presented in this proposed rule.

Number of Suppliers

The number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, while volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. Instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. We also did not find any correlation between number of suppliers and SPA or maximum winning bid amount.

We are soliciting comments on these findings.

B. Current Issues

1. Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas During a Gap in the DMEPOS CBP

As indicated in section V.D.2 of section V "Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)" of the proposed rule, we are proposing to make changes to the DMEPOS CBP effective January 1, 2019. The proposed changes to the CBP would be effective for competitions beginning on or after January 1, 2019. The Round 2 Recompete, National Mail-Order Recompete, and Round 1 2017 contract periods of performance will end on December 31, 2018. Competitive bidding for items furnished on or after January 1, 2019 has not yet begun, and therefore, we do not expect that CBP contracts would be in place on January 1, 2019. Thus we anticipate that there would be a gap in the CBP beginning January 1, 2019. During a gap in the CBP beginning January 1, 2019, there would be no contract suppliers and payment for all items and services previously included under the CBP would be based on the lower of the supplier's charge for the item or fee schedule amounts adjusted in accordance with sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. We are proposing specific fee schedule adjustments as a way to temporarily pay for items and services in the event of a gap in the CBP due to CMS being unable to timely recompete CBP contracts before the current

DMEPOS competitive bidding contract periods of performance end.

We are proposing three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or noncontiguous areas.

With regard to section 16008 of the Cures Act, we have taken the information mandated by section 16008 of the Cures Act into account as part of developing the proposed fee schedule adjustments for items and services furnished on or after January 1, 2019 through December 31, 2020, in areas that are currently non-CBAs. Section 16008 of the Cures Act first mandates that we take stakeholder input into account in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished beginning in 2019. The information we have collected includes input from many stakeholders indicating that the fully adjusted fee schedule amounts are too low and that this is having an adverse impact on beneficiary access to items and services furnished in rural and remote areas. Industry stakeholders have stated that the fully adjusted fee schedule amounts are not sufficient to cover the supplier's costs, particularly for delivering items in rural, remote areas. We are monitoring outcomes, assignment rates, and other issues related to access of items and services such as changes in allowed services and number of suppliers. We believe it is important to continue monitoring these things before proposing a more long term fee schedule adjustment methodology using information from the CBP. If fee schedule amounts are too low, they could impact access and potentially damage the businesses that furnish DMEPOS items and services. If fee schedule amounts are too high, this increases Medicare program and beneficiary costs unnecessarily. For these reasons, we believe that we should proceed cautiously in developing fee

schedule adjustment methodologies for the short term that can protect access to items, while we continue to monitor and gather data and information. We plan to address fee schedule adjustments for items furnished on or after January 1, 2021 in future rulemaking after we have continued to monitor health outcomes, assignment rates, and other information.

Section 16008 of the Cures Act mandates that we take into the account the highest amount bid by a winning supplier in a CBA. However, as previously discussed in section VI.A.2 of this proposed rule, the highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others). Thus, we did not find any supporting evidence for the development of a payment methodology for the non-CBAs based on the highest winning bids in a

Section 16008 of the Cures Act mandates that we take into account a comparison of the average travel distance and cost associated with furnishing items and services in the area. We found that the average travel distance and cost for suppliers in non-CBAs is generally lower than the average travel distance and cost for suppliers in CBAs. However, oftentimes costs in the non-contiguous areas of the U.S., particularly in Hawaii and Alaska, were higher than costs in the contiguous areas of the U.S., for most of the cost data that we examined and presented in this rule. As noted in section VI.A.1 of this proposed rule, this was confirmed by one commenter who stated that noncontiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Additionally, from our analysis presented in this rule, the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as FAR, OCBSAs, and super rural areas, suppliers, on average, must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs. Thus, we believe this supports a payment methodology that factors in the increased costs in noncontiguous areas, and the increased travel distance suppliers face in reaching certain rural areas.

Section 16008 of the Cures Act mandates that we take into account a comparison of the average volume of items and services furnished by suppliers in the area. We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items is higher in CBAs than non-CBAs. We believe this finding supports a payment methodology that factors in and ensures beneficiary access to items and services in non-CBAs with relatively low volume.

Finally, section 16008 of the Cures Act mandates that we take into account a comparison of the number of suppliers in the area. According to Medicare claims data, the number of supplier locations furnishing DME items and services subject to the fee schedule adjustments decreased by 22 percent from 2013 to 2016. In 2016 alone there was a little over 6 percent decline from the previous year in the number of DME supplier locations furnishing items and services subject to the fee schedule adjustments. The magnitude of this decline in DME supplier locations, from 13,535 (2015) to 12,617 (2016), indicates that the number of DME supplier locations serving these areas continues to decline. There has been a further reduction in supplier locations of 9 percent in 2017. We can attribute a certain percentage of this decline in the number of suppliers to audit, investigation, and evaluations by CMS and its contractors to enhance fraud and abuse controls to monitor suppliers. Furthermore, we have noted in section VI.A.6 of this proposed rule that instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. Additionally, while the number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. However, we are still concerned about the potential beneficiary access issues that might occur in more rural and remote areas based on this consistent decline in number of suppliers. As such, out of an abundance of caution, we believe that the consistent decline in number of suppliers supports adjusting the fee schedule amounts in a way that seeks to abate this declining trend and ensure access to items and services for beneficiaries living in rural areas and other remote areas such as Alaska,

Hawaii, Puerto Rico and other U.S. territories.

Based on the stakeholder comments, the higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and the decrease in the number of non-CBA supplier locations, we believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently rural or non-contiguous non-CBAs, should be based on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of §414.210(g). We believe that since the information from the CBP comes from bidding in non-rural areas only and in all but one case in areas located in the contiguous U.S., that full adjustments based on this information should not be applied to fee schedule amounts for items and services furnished in rural and non-contiguous areas on or after January 1, 2019. We believe that blended rates can help ensure beneficiary access to needed DME items and services in rural, remote and non-contiguous areas and better account for the differences in costs for these areas versus more densely populated areas. We believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently non-CBAs, but are not rural or non-contiguous areas, should be based on 100 percent of the adjusted fee schedule amounts in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). Although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. Because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, we believe the fully adjusted fee schedule amounts are sufficient. However, we request specific comments on the issue of whether the 50/50 blended rates should apply to these areas as well.

In the event that the proposal outlined in section V "Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)", to change the method for calculating SPAs

under the CBP is finalized and SPAs under future competitions are calculated based on maximum winning bids rather than the median of winning bids, this change in payments under the CBP may warrant further changes to the fee schedule adjustment methodologies under § 414.210(g)(1) through (8). We would address further changes to the fee schedule adjustment methodologies in future rulemaking.

In summary, based on stakeholder input, the higher costs for suppliers in non-contiguous areas, the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of non-CBA supplier locations, we are proposing to revise § 414.210(g)(9) and to adjust the fee schedule amounts for items and services furnished in rural and noncontiguous non-CBAs by extending through December 31, 2020, the current methodology which bases the fee schedule amounts on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amount in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). We are proposing to adjust the fee schedule amounts for items and services furnished in non-rural and contiguous non-CBAs from January 1, 2019 through December 31, 2020, using the current methodologies under paragraphs (1) through (8) of § 414.210(g). We plan to continue monitoring health outcomes, assignment rates, and other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after January 1, 2021, in future rulemaking.

2. Proposed Fee Schedule Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During a Gap in the DMEPOS CBP

In the event of a future gap in the CBP due to CMS being unable to timely recompete contracts under the program before the DMEPOS competitive bidding contract periods of performance end, we are proposing a fee schedule adjustment methodology that would be used to adjust the fee schedules for items and services that are currently subject to and included in competitive bidding programs. We believe that a fee schedule adjustment methodology for items and services furnished during a gap in the CBP in areas that were included in the CBP should result in rates comparable to the rates that would otherwise be established under the CBP in order to maintain the level of savings

that would otherwise be achieved if the CBP was in effect. We are proposing a specific fee schedule adjustment methodology for items and services furnished within former CBAs in accordance with sections 1834(a)(1)(F) and 1834(a)(1)(G) of the Act. Specifically, we propose to add a new paragraph (10) under § 414.210(g) that would establish a methodology for adjusting fee schedule amounts paid in areas that were formerly CBAs during periods when there is a temporary lapse in the CBP. We propose to adjust the fee schedule amounts for items and services furnished in former CBAs based on the SPAs in effect in the CBA on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the CPI for all Urban Consumers (CPI-U) for the 12-month period on the date after the contract periods ended (for example, January 1, 2019). If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day after the contract period ended based on the projected percentage change in the CPI-U for the 12-month period ending on the anniversary date.

We also propose to revise paragraph (4) under § 414.210(g), so that it does not conflict with the proposed new paragraph (10), by revising the first sentence in paragraph (4) to read: "In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the

fee schedule amounts."

With regard to payment for non-mail order diabetic testing supplies, section 1834(a)(1)(H) of the Act mandates that payment for non-mail order diabetic testing supplies be equal to the SPAs established under the national mail order competition for diabetic testing supplies. We believe that as of January 1, 2019, we must continue payment for non-mail order diabetic supplies at the current SPA rates. These SPA rates would not be updated by inflation adjustment factors and would remain in effect until new SPA rates are established under the national mail order program. We do not believe that this statutory provision would cease to apply in situations where there is a gap in the national mail order competitions for diabetic testing supplies; and therefore, we will continue to use the SPAs for mail order diabetic testing supplies as the payment amounts for

non-mail order diabetic testing supplies in the event that there is a gap in the CBP.

We seek comments on these proposals.

C. Provisions of the Proposed Rule

We are proposing to revise the fee schedule adjustment methodology at $\S414.210(g)(9)$ so that for items and services furnished in non-CBAs that are rural or non-contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount. We are proposing to revise the fee schedule adjustment methodology at § 414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

We also propose a methodology for adjusting the fee schedule amounts for items and services that are currently subject to competitive bidding furnished in former CBAs in the event of a lapse in the DMEPOS CBP. We propose to create a new paragraph (10) under § 414.210(g) titled "Payment Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During Temporary Gaps in the DMEPOS CBP" that has the following text underneath: "During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI-U for the 12-month period ending on the anniversary date.'

Finally, with regard to payment for non-mail order diabetic testing supplies in the event of a gap in the CBP, payment would continue at the SPA rates for mail order diabetic testing supplies as mandated by section 1834(a)(1)(H) of the Act. We would pay for non-mail order diabetic supplies at the current SPA rates until new rates are established under the national mail order program.

VII. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

A. Background

The Medicare payment rules for durable medical equipment are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. In general, Medicare payment for DME items and services paid on a fee schedule basis is equal to 80 percent of the lower of either the actual charge or the fee schedule amount for the item. The beneficiary coinsurance is equal to 20 percent of the lower of either the actual charge or the fee schedule amount for the item. General payment rules for DME are set forth in section 1834(a)(1) of the Act and § 414.210 of our regulations, and § 414.210 also contains paragraphs relating to maintenance and servicing of items and replacement of items. Specific payment rules for oxygen and oxygen equipment are set forth in section 1834(a)(5) of the Act and § 414.226 of our regulations. The average monthly payment to suppliers serving beneficiaries with a prescribed flow rate of greater than 4 liters per minute in 2006 was approximately \$299.76. Before the enactment of the Deficit Reduction Act of 2005 (DRA), these monthly payments continued for the duration of use of the equipment, provided that Medicare Part B coverage and eligibility criteria were met. Medicare covers three types of oxygen delivery systems: (1) Stationary or portable oxygen concentrators, which concentrate oxygen in room air; (2) stationary or portable liquid oxygen systems, which use oxygen stored as a very cold liquid in cylinders and tanks; and (3) stationary or portable gaseous oxygen systems, which administer compressed oxygen directly from cylinders. There is also transfilling equipment that takes oxygen from concentrators and fills up small portable gaseous tanks. Both liquid and gaseous oxygen systems require delivery of oxygen contents. Concentrators and transfilling systems do not require delivery of oxygen contents. Medicare payment for furnishing oxygen and oxygen equipment is made on a monthly basis and the fee schedule amounts vary by State.

Effective January 1, 2006, section 5101(b) of the DRA amended section

1834(a)(5) of the Act, limiting the monthly payments for oxygen equipment to 36 months of continuous use. The limit of 36 months of payment also applies to cases where there is an oxygen flow rate of greater than 4 liters per minute. The DRA mandated that payment for the delivery of oxygen contents continue after the 36-month cap on payments for oxygen equipment. At this time, Medicare already had an established fee schedule amount or payment class for oxygen contents only for beneficiaries who owned the stationary and/or portable oxygen equipment. The monthly payment for oxygen contents for beneficiaries who purchased oxygen equipment prior to 1989 included payment for delivery of both stationary and portable contents and was approximately \$156 on average in 2006. CMS implemented section 1834(a)(5) of the Act, as amended by section 5101 of the DRA, in the final rule published on November 9, 2006 in the Federal Register, titled "Home Health Prospective Payment System Rule Update for Calendar Year 207 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment", (71 FR 65884). As part of this rule, we amended § 414.226 by adding a new paragraph (c) and separate payment classes for: Oxygen generating portable equipment (OGPE) consisting of portable oxygen concentrators and transfilling equipment that met the patient's portable oxygen needs without relying on the delivery of oxygen contents; stationary oxygen contents after the 36month rental period; and portable oxygen contents after the 36-month rental period. With the addition of the new class for OGPE, rather than receiving the standard monthly add-on payment of \$31.79 for portable oxygen equipment, we established a higher amount of \$51.63 per month for this new technology as opposed to furnishing portable gaseous or liquid oxygen equipment, which continued to be paid at the lower add-on payment rate of \$31.79 per month.

Section 1834(a)(9)(D) of the Act provides the authority to create separate classes of oxygen and oxygen equipment. Section 1834(a)(9)(D)(ii) of the Act mandates that new, separate classes of oxygen and oxygen equipment be budget neutral; the Secretary may establish new classes for oxygen and oxygen equipment only if the establishment of such classes does not result in expenditures for any year that are less or more than the expenditures which would have been made had the

classes not been established. It is important to stress that the budget neutrality requirement in section 1834(a)(9)(D)(ii) of the Act applies regardless of whether fee schedule amounts are adjusted based on information from the DMEPOS CBP. As long as suppliers continue to get paid more for OGPE than they would otherwise be paid had the OGPE class not been established, a methodology must be employed to ensure that payments or expenditures overall are budget neutral. Since 2008, in accordance with our regulations at § 414.226(c), CMS has ensured budget neutrality each year by determining how much expenditures increased as a result of the higher paying OGPE class and reducing the monthly payment amount for stationary oxygen equipment and oxygen contents by a certain percentage to offset the increase in payments attributed to the higher amount paid for OGPE. Stakeholders have argued that the budget neutrality requirement should no longer apply in situations where the fee schedule amounts for oxygen and oxygen equipment, including the fee schedule amounts for OGPE, are adjusted based on information from the DMEPOS CBP. However, as long as the add-on payment amounts for OGPE are higher than the add-on payment amounts that would otherwise have been made for portable oxygen equipment in general, a budget neutrality offset is needed to ensure the OGPE class does not result in total expenditures for any year which are more or less than the expenditures which would have been made if the payment class had not been established.

As of January 1, 2018, the average adjusted fee schedule monthly add-on amount for OGPE was \$40.08 and for portable gaseous and liquid oxygen equipment was \$18.20. Either of these monthly add-on amounts is added to the average adjusted fee schedule monthly payment for stationary oxygen equipment and oxygen contents which was \$72.95. We note that if the fee schedule amounts for oxygen and oxygen equipment are adjusted based on information from the DMEPOS CBP, and these adjustments result in the fees for OGPE being lower than the add-on payment amounts that would otherwise have been made for portable oxygen equipment in general, a positive rather than a negative budget neutrality offset would be needed to ensure that total expenditures for any year are not more or less than the expenditures which would have been made if the payment class had not been established.

B. Provisions of the Proposed Rule

1. Adding a Portable Liquid Oxygen Equipment Class

The current payment classes for oxygen and oxygen equipment are included in § 414.226(c), and include: (i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable); (ii) Portable equipment only (gaseous or liquid tanks); (iii) OGPE only; (iv) Stationary oxygen contents only; and (v) Portable oxygen contents only.

As explained earlier in the preamble, the add-on payment for OGPE is higher than the add-on payment for portable gaseous and liquid equipment. OGPE provides advantages for beneficiaries in that they do not need to rely on the delivery of oxygen contents, in contrast to beneficiaries using portable gaseous or liquid equipment. The OGPE systems are also more lightweight and therefore allow for greater ambulation for beneficiaries who cannot carry or push heavier equipment. Since adding the higher paying OGPE class, utilization of this equipment has doubled, use of portable gaseous equipment declined slightly, while use of portable liquid equipment dropped significantly and now accounts for only 2 percent of utilization of portable oxygen equipment. Although portable liquid oxygen equipment does not eliminate the need for delivery of oxygen contents, it is a more lightweight system like OGPE and promotes ambulation in beneficiaries. It is also more expensive than portable gaseous equipment to suppliers, beneficiaries, and the Medicare program. The higher payments and incentives for furnishing OGPE have in essence created a disincentive to furnish portable liquid equipment.

This proposed rule would amend our regulations at § 414.226 by using the authority at section 1834(a)(9)(D) to add separate payment classes for portable gaseous oxygen equipment only and portable liquid oxygen equipment only. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we propose splitting this class into two classes and increasing the add-on amount for portable liquid oxygen equipment. We propose establishing the initial add-on amounts for portable liquid oxygen equipment so that they are equal to the add-on amounts for OGPE, thus reducing the incentive to furnish OGPE over portable liquid oxygen equipment. The add-on payment amounts would be adjusted in the future based on pricing information from the DMEPOS CBP. As explained above, section 1834(a)(9)(D)(ii) of the

Act mandates that these new classes be annually budget neutral; however, we do not expect this change to result in a dramatic increase in the use of portable liquid oxygen equipment, and so we do not believe the budget neutrality offset would be significant.

Suppliers furnishing oxygen and oxygen equipment in a CBA under the DMEPOS CBP must furnish portable liquid oxygen equipment in any case where a beneficiary starting a new 36month period of continuous use for oxygen and oxygen equipment requests portable liquid oxygen equipment. This is because all of the HCPCS codes describing the different types of oxygen and oxygen equipment are items included in the respiratory equipment product category under the DMEPOS CBP and § 414.422(e)(1) requires that that a contract supplier agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. However, suppliers in non-CBAs are not required to furnish portable liquid oxygen equipment even if a beneficiary requests such equipment from a supplier, which is why we believe it is important to eliminate any disincentives for furnishing this modality that may result because of higher payments for OGPE. Thus, we believe that adding the portable liquid oxygen equipment class and adding a provision to the regulations that would ensure that the payment amount for portable liquid oxygen equipment is the same as OGPE would encourage suppliers to furnish this modality when it is requested by beneficiaries.

2. Adding a Liquid High-Flow Oxygen Contents Class

As explained above, the statute allows a 50 percent volume adjustment add-on payment to suppliers for furnishing oxygen and oxygen equipment to beneficiaries with a prescribed oxygen flow rate of more than 4 liters per minute. This provides additional payment for equipment and/or delivery of additional contents necessary to meet the needs of beneficiaries who are prescribed a large quantity of oxygen. However, this add-on payment is tied to the payment for stationary equipment, which is capped after 36 months of continuous use. Certain oxygen concentrators are capable of meeting the high flow needs of some beneficiaries and continue to be available after the 36-month cap on payments for oxygen equipment. In addition, transfilling machines can be used to fill multiple lightweight portable canisters and continue to be available after the 36month cap on payments for oxygen equipment.

Section 1834(a)(5)(F)(ii)(II) of the Act requires that Medicare continue to make monthly payments for the delivery and refilling of oxygen contents for the period of medical need after 36 months of continuous use. Currently, there are two classes for oxygen contents (gaseous and liquid), one for stationary oxygen contents and the other for portable oxygen contents—see § 414.226(iv) and (v). In a limited number of cases where a patient is ambulatory and is prescribed a very high flow rate of oxygen (generally greater than 6 liters per minute), a portable liquid oxygen system is the only modality that would meet their high flow, portable oxygen

needs. In order to better ensure that these beneficiaries have access to the portable liquid oxygen contents necessary to meet their high flow needs, we propose to add a new separate class for "portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute."

We propose to establish the initial fee schedule amounts for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute by multiplying the fee schedule amounts for portable oxygen contents by 1.5 to increase the payment amount by 50 percent above the payment amount for portable oxygen contents. Like the other classes of oxygen and oxygen equipment, the fee schedule amounts

for this class would be adjusted in the future based on pricing information from the DMEPOS CBP. As explained above, section 1834(a)(9)(D)(ii) of the Act mandates that this new class be annually budget neutral; however, we expect that this change will have a very minimal impact on expenditures due to the limited number of beneficiaries who require a high flow rate for oxygen and can still ambulate. Therefore, we do not believe the budget neutrality offset needed would be significant.

Table 53 compares the current classes of oxygen and oxygen equipment and the proposed classes of oxygen and oxygen equipment.

TABLE 53—CURRENT AND PROPOSED OXYGEN AND OXYGEN EQUIPMENT CLASSES

| Current oxygen and oxygen equipment: 5 classes described in 414.226 | Proposed oxygen and oxygen equipment: 7 classes |
|--|--|
| Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable). Portable equipment only (gaseous or liquid tanks) | Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable). Portable gaseous equipment only. Portable liquid equipment only. |
| Oxygen generating portable equipment only. Stationary oxygen contents only Portable oxygen contents only | Oxygen generating portable equipment only. Stationary oxygen contents only. Portable gaseous and liquid oxygen contents only except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute. Portable liquid oxygen contents only for prescribed flow rates greater than four liters per minute. |

3. Applying Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

In accordance with section 1834(a)(9)(D)(ii) of the Act, the fee schedule amounts for the oxygen and oxygen equipment classes are set in a budget neutral manner for each oxygen and oxygen equipment HCPCS code. The budget neutrality offset necessary to maintain the separate class for OGPE has been exclusively applied to the stationary oxygen equipment fee schedule amount as indicated in § 414.226(c)(6). We propose to change § 414.226(c)(6) and the methodology for applying the budget neutrality offset, in addition to adding the two new oxygen

and oxygen equipment classes proposed above. Rather than applying the budget neutrality offset to the payment for stationary equipment and oxygen contents only, we propose to apply the budget neutrality offset to all oxygen and oxygen equipment classes and HCPCS codes beginning January 1, 2019. To implement our proposal, a budget neutrality offset shall be applied to all HCPCS codes for oxygen equipment and oxygen contents, thereby lowering the amount of the offset applied specifically to payments for stationary oxygen. We consider applying the budget neutrality offset to all oxygen classes instead of just the stationary oxygen equipment class to be more equitable in that it would not just

lower payments for suppliers of stationary oxygen equipment (some of which may never furnish OGPE), but would spread the budget neutrality offset more equitably across all classes and codes for oxygen and oxygen equipment. Table 54 is an example of the fee schedule amounts when the budget neutrality offset is applied only to the stationary oxygen equipment rate versus applying the budget neutrality offset to all oxygen classes. This particular example depicts fully adjusted fee schedule amounts, including budget neutrality adjustments, for oxygen and oxygen equipment furnished in non-rural areas in the Southeast U.S.

TABLE 54—JANUARY 1, 2018 FEES FOR CURRENT AND PROPOSED BUDGET NEUTRALITY METHODS

| Current method | 2018 rate | Proposed method | 2018 rate |
|---|-----------|---|----------------|
| Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable). | \$70.23 | Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable). | \$72.59 |
| Portable equipment only (gaseous or liquid tanks) | 17.29 | Portable gaseous equipment only | 16.04 34.73 |
| Oxygen generating portable equipment onlyStationary oxygen contents only | | Oxygen generating portable equipment only Stationary oxygen contents only | 34.73 49.46 |

TABLE 54—JANUARY 1, 2018 FEES FOR CURRENT AND PROPOSED BUDGET NEUTRALITY METHODS—Continued

| roposed method 2018 rate |
|---|
| and liquid oxygen contents only n of portable liquid contents greatper minute. tents only greater than four liters 74.19 |
| tior ers |

We solicit comments on these provisions.

VIII. Payment for Multi-Function Ventilators

A. Background

Section 1834(a) of the Act governs payment for DME covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule amounts for items under each of the categories are established. More importantly, the payment rules for these categories are different and in some cases mutually exclusive. Table 55

provides a summary of the payment categories, corresponding payment methodology, and statutory and regulatory sections. The main payment categories are: Inexpensive or other routinely purchased items, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, and other items of DME (capped rental). Some differences in the payment rules for the payment categories arise, for example, where sections 1834(a)(2), (4), (6), and (7) of the Act allow for the lump sum purchase of certain items paid under these categories, while sections 1834(a)(3) and (5) of the Act do not allow for lump sum purchase of items in those categories. Also, sections 1834(a)(2), (5), and (7) of the Act cap or limit total rental payments for items paid under these categories, whereas

section 1834(a)(3) does not. With regard to rented items, section 1834(a)(7) of the Act mandates beneficiary ownership of the item after 13 months of continuous rental, whereas sections 1834(a)(2), (3), and (5) do not require transfer of ownership to the beneficiary. Finally, section 1834(a)(3) of the Act mandates that payment for covered items such as ventilators and intermittent positive pressure breathing machines be made on a monthly basis for the rental of the item, whereas ventilators that are either continuous positive airway pressure devices or intermittent assist devices with continuous positive airway pressure devices are excluded from section 1834(a)(3) of the Act. Respiratory assist devices, suction pumps (aspirators), and nebulizers fall under section 1834(a)(7) of the Act.

TABLE 55—SUMMARY OF DME EQUIPMENT PAYMENT CATEGORIES AND RULES

| Payment category | Payment rules |
|--|--|
| Inexpensive or other routinely pur- chased items—section 1834(a)(2) of the Act | Purchase price of \$150 or less, OR were routinely purchased (75 percent of the time or more) under the rent/purchase program prior to 1989, OR are speech generating devices, OR are accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices, respiratory assist devices, or speech generating devices. If covered, these items can be purchased new or used and can be rented; however, total payments cannot exceed the purchase new fee for the item. See 42 CFR 414.220. |
| Items requiring frequent and sub- stantial servicing—section 1834(a)(3) of the Act | Items, such as ventilators, requiring frequent and substantial servicing, in order to avoid risk to the patient's health. If covered, these items can be rented as long as they are medically necessary with the supplier retaining ownership of the equipment. Payment is generally made on a monthly rental basis with no cap on the number of rental payments made as long as medically necessary. Excludes CPAP devices, respiratory assist devices, suction pumps/aspirators, and nebulizers. See 42 CFR 414.222. |
| Customized items—section 1834(a)(4) of the Act | Payment amounts are not calculated for a customized DME item. Customized DME is defined at 42 CFR 414.224, including customized wheelchairs. If covered, payment is made in a lump-sum amount for the purchase of the item based on the DME Medicare Administrative Contractor (MAC), Part A MAC, or Part B MAC's individual determination. See 42 CFR 414.224. |
| Oxygen and oxygen equipment—section 1834(a)(5) of the Act | One bundled monthly rental payment amount is made, not to exceed a 36 month cap, for all covered stationary equipment, stationary and portable contents, and all accessories used in conjunction with the oxygen equipment. An add-on payment may also be made for portable oxygen. After 36 months, payment can continue to be made on a monthly basis for oxygen contents for liquid or gaseous oxygen equipment. Payment for in-home maintenance and servicing of supplier-owned oxygen concentrators and transfilling equipment may be made every 6 months, beginning 6 months after the 36 month rental cap, for any period of medical need for the remainder of the reasonable useful lifetime of the equipment (5 years). See 42 CFR 414.226. |
| Other Covered Items (Other than DME)—section 1834(a)(6) of the Act | Payment under a lump sum purchase. |
| Other items of DME (capped rental items)—section 1834(a)(7) of the Act | Monthly rental payment amount is made not to exceed a 13 month cap at which point the beneficiary takes over ownership of the equipment. Complex rehabilitative power wheelchairs can be purchased in the first month of use. For capped rental items other than power wheelchairs, the payment amount is calculated based on 10 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the payment amount is equal to 7.5 percent of the purchase price. For power wheelchairs, the rental payment amount is calculated based on 15 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the fee schedule amount is equal to 6 percent of the purchase price. See 42 CFR 414.229. |

The Medicare allowed amount for DMEPOS items and services paid on a fee schedule basis is equal to the lower of the supplier's actual charge or the fee schedule amount. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

B. Current Issues

Concerns have been raised by the manufacturer of a multi-function ventilator about how the separate

payment categories set forth at sections 1834(a)(2) through (a)(7) of the Act would apply to a new type of ventilator, which consists of a ventilator base item classified under section 1834(a)(3) of the Act, but can also perform the function of portable oxygen equipment classified under the payment categories in sections 1834(a)(5), and the functions of a nebulizer, a suction pump, and a cough stimulator classified under paragraph (7) of section 1834(a) of the Act. For example, a new product was recently cleared by the Food and Drug Administration (FDA) as a ventilator, but can also function as a portable oxygen concentrator, nebulizer, suction pump (aspirator), and cough stimulator. The multi-function ventilator assists

with serving multiple, different medical needs of beneficiaries with diagnoses such as chronic lung disease, cystic fibrosis, ALS, and muscular dystrophy. As shown in Table 56, separate DME items perform each of these functions, and the DME items that perform these functions have already been assigned separate HCPCS codes and payment amounts under the DMEPOS fee schedule. Currently, HCPCS codes E0465 and E0466 are denoted for a home ventilator item, any type, used with either an invasive interface (for example, tracheostomy tube) or noninvasive interface (for example, mask, chest shell). Portable oxygen concentrators are identified using a combination of codes E1390 plus E1392.

TABLE 56—FUNCTIONS, PAYMENT CATEGORY, AND HCPCS FOR FUNCTIONS OF A MULTI-FUNCTION VENTILATOR

| HCPCS code | Function | Payment category |
|--------------------------|--------------|---|
| E1390 and E1392 E0570 | Suction Pump | Capped rental items. Capped rental items. |

We noted other concerns while considering how to categorize and pay for the multi-function ventilator. One concern is that a patient may not need all of the functions that the new multifunction ventilator performs, and there are different Medicare medical necessity coverage criteria for each of the five different functions typically performed by five different pieces of equipment. In addition, another concern we have is while section 1847(a)(2)(A) of the Act mandates the implementation of competitive bidding for covered items, the only items that comprise the multifunction ventilator that have been phased into the DMEPOS CBP at this time are portable oxygen concentrators and nebulizers. As a result, in CBAs, only contract suppliers can furnish portable oxygen concentrators or nebulizers to beneficiaries in these areas, whereas non-contract suppliers can furnish ventilators, suction pumps, and cough stimulators in these same areas. The current competitive bid product categories do not include a single item, furnished by one supplier, which performs the functions of five separate items, as the multi-function ventilator does. Upon determination that the multi-function ventilator is a covered item within the meaning of section 1834(a)(13) of the Act and its payment category, the multi-function ventilator item can be eligible for

inclusion in a CBP along with other ventilator items.

To address these concerns, we reviewed the payment rules for ventilators. Section 1834(a)(1)(C) of the Act indicates that subsection (a) of section 1834 is the exclusive payment rule for these items; however, this subsection does not specifically set forth a payment category for DME items that are capable of performing the functions of other items that can be classified under the multiple, different payment categories and accompanying rules under sections 1834(a)(2) through (7) of the Act. Similarly, the regulations at 42 CFR 414.220 through 42 CFR 414.229 and program instructions currently do not address payment for the multifunction ventilator's additional functions. In addition, there is no guidance or criteria regarding how to determine which function of a new multi-function item should determine the payment category for the entire multi-function item. Furthermore, because the supplier is only furnishing one item and the patient may not need more than one of the functions/features for the duration of time the item is used by the patient, we do not believe payment should be established by summing the current separate payment amounts for each function (ventilators, oxygen concentrators, nebulizers, suction pumps, and cough stimulators)

to determine the fee schedule amount for the integrated multi-function item.

We believe we should classify multifunction ventilators in the frequent and substantial servicing payment category under section 1834(a)(3) of the Act and address payment for these ventilators that can perform multiple functions. The information we gathered during our review supports our proposal to classify these items under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act. Multifunction ventilators are classified by the FDA as ventilators, instead of oxygen concentrators, nebulizers, suction pumps, or cough stimulators. We believe that section 1834(a)(1)(C) of the Act requires that DME be classified into one of the payment categories in section 1834(a)(2) through (7) of the Act. We believe that by classifying these items under section 1834(a)(3) of the Act and not under sections 1834(a)(2), (4), (5), (6), or (7) of the Act, that only the rules under section 1834(a)(3) would apply to these items. We believe this is appropriate and propose to establish fee schedule amounts for multi-function ventilators based on the current Medicare fee schedule amounts for ventilators plus an additional amount for the average cost of the various additional functions or features the equipment offers (oxygen concentration, drug nebulization, respiratory airway suction, and cough stimulation). This is

similar to how fee schedule amounts have been established for other DME items in the past, such as using the average of allowed charges for underarm crutches with shock absorbers and allowed charges for underarm crutches without shock absorbers to establish the fee schedule amounts for underarm crutches with or without shock absorbers (HCPCS code E0116), or using the average of allowed charges for walkers with a fixed height and allowed charges for walkers with an adjustable height to establish the fee schedule amounts for walkers with or without adjustable heights (HCPCS codes E0130 through E0143).

C. Provisions of the Proposed Rule

Based on our review, we are proposing to add a provision to the regulation at § 414.222(f) to establish a payment methodology for multifunction ventilators effective for dates of service on or after January 1, 2019. We believe that our proposal complies with the Medicare payment rules for DME in section 1834(a) of the Act, while recognizing and encouraging innovations in technology such as multi-function ventilators. These devices can enhance patient care and promote ambulation by eliminating the need for the patient to be tethered to several pieces of equipment. We propose that multi-function ventilators

be classified under section 1834(a)(3) of the Act. Items classified under section 1834(a)(3) of the Act are paid on a continuous monthly rental basis. We are interested in receiving comments on alternatives to the approach we are taking regarding the proposed classification and payment of multifunction ventilators.

We propose to establish the monthly rental fee schedule amounts for a multifunction ventilator based on the existing monthly rental fee schedule amounts for ventilators plus payment for the average cost of the additional functions. Under this proposal, a single monthly rental fee schedule amount shall be paid to encompass the base ventilator item and its additional functional components as follows.

- The monthly rental fee schedule amount for a multi-function ventilator is equal to the monthly rental fee schedule amount for a ventilator established in § 414.222(c) and (d) plus the average of the lowest monthly cost for one additional function and the monthly cost of all additional functions, increased by the annual coverage item updates of section 1834(a)(14) of the Act.
- The monthly cost for additional functions shall be determined as follows:
- For functions performed by items classified under § 414.222 prior to 1994

the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

- For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment. There are currently no multi-function ventilators on the market that perform the function for items classified under § 414.220.
- For functions performed by items classified under § 414.226 for oxygen equipment, the monthly cost is equal to the monthly payment amount established in § 414.226(e), (f), and (g), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.
- For functions performed by items classified under § 414.229 for cough stimulator, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

TABLE 57—PROPOSED PAYMENT METHOD FOR MULTI-FUNCTION VENTILATORS [Example]

| Step | Method | HCPCS codes |
|------------|--|------------------------|
| (1) (2) | | E0465 or E0466 |
| (a) | (Portable Oxygen Concentrator monthly fee schedule amount × 36 months)/60 months * | E1392 + E1390 E0570 |
| (c) | CY 1993 Suction Pump monthly rental fee schedule amount × covered item update factor for DME to CY 2019**. | E0600 |
| (3)(4) | (Cough Stimulator newly purchased fee schedule amount)/60 months * | E0482 |

^{*5} year (60 months) reasonable useful lifetime of the equipment.

Medicare coverage and payment can be available for multi-function ventilators furnished to beneficiaries who are prescribed a multi-function ventilator and meet the Medicare medical necessity coverage criteria for a ventilator and at least one of the four additional functions of the device. The fee schedule amount for the multifunction ventilator would be determined in advance for each calendar year and would not vary regardless of how many additional functions the beneficiary needs in addition to the ventilator function. We are proposing that the payment amount would be established for CY 2019 and then updated each year after 2019 using the covered item update factors mandated by section 1834(a)(14) of the Act. In the event that a patient is furnished a multi-function ventilator and only meets the Medicare medical necessity coverage criteria for a

ventilator, Medicare coverage and monthly rental payments would be for the ventilator only, and payment could not be made for the other functions of the device.

We are proposing a payment method that we believe ensures an integration of the functions of the multi-function ventilator with a bundled corresponding payment amount that addresses additional functions of the items that are necessary for patient care. If a

^{**} The monthly rental amounts paid prior to 1994 included payment for the equipment and all related accessories.

beneficiary is furnished a multi-function ventilator, payment would be denied for any separate claims for oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories, and cough stimulators and any related accessories. Thus, our proposal prevents division of the multi-function item into separate parts with separate fee schedule amounts for each function of the item, some of which have conflicting payment rules. Also, this proposed payment method lessens confusion for the supplier which could occur if the supplier were to receive varying monthly rental amounts for a multifunction item and instead permits a supplier to receive predictable monthly payments over the 60 month reasonable useful lifetime of the multi-function ventilator.

We are not proposing § 414.222(f) to apply to other DME items. Subsequent rulemaking would be necessary to address other multi-function items.

We are soliciting comments on this proposal.

IX. Including the Northern Mariana Islands in Future National Mail Order CRPs

A. Background

In our CY 2015 ESRD PPS final rule (79 FR 66223 through 66265), we said that while section 1847(a)(1)(A) of the Act provides that CBPs be established throughout the U.S., the definition of U.S. at section 210(i) of the Act does not include the Northern Mariana Islands. We therefore previously determined that the Northern Mariana Islands are not considered an area eligible for inclusion under a national mail order CBP. We finalized a proposal regarding fee schedule adjustments based on information from the national mail order program and the Northern Mariana Islands at $\S414.210(g)(7)$ to provide that the fee schedule amounts for mail order items furnished in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts (SPAs) established under a national mail order program. We discussed how a few commenters recommended waiting for the second round of bidding for the national mail order CBP before adjusting the fee schedule amounts for mail order items furnished in the Northern Mariana Islands in order to allow more time to determine if the competitive bidding payment amounts allow for access to items and services and to acquire more pricing points over an extended period of time. The commenters further recommended increasing payment

amounts for the national mail order SPA for the Northern Mariana Islands to limit any access or pricing complications. In response, we said we disagreed with these suggestions, and that the national mail order SPAs already applied to items shipped to various remote areas of the U.S. and have not resulted in any problems with access to mail order items in these areas. Therefore, we believed the SPAs could be used to adjust the mail order fee schedule amounts for the Northern Mariana Islands effective January 1, 2016.

B. Current Issues

The national mail order program for diabetic testing supplies is currently in effect in all areas of the U.S., except for the Northern Mariana Islands. Thus, the Northern Mariana Islands are currently the only non-CBA for mail order diabetic testing supplies. However, even though the Northern Mariana Islands are currently not included in the national mail order program, per § 414.210(g)(7), CMS currently pays for mail order items furnished in the Northern Mariana Islands at 100 percent of the SPAs established under the national mail order CBP. After further examining this issue, it is now our view that the Northern Mariana Islands are an area eligible for inclusion under a national mail order CBP. A Joint Resolution addressing the Northern Mariana Islands titled "Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America" was approved in 1976 (Pub. L. 94-241 (HIRes 549), 90 Stat 263, March 24, 1976). The Joint Resolution addresses the applicability of certain federal laws to the Northern Mariana Islands. Article V ("Applicability of Laws"), section 502(a) specifies:

"The following laws of the United States in existence as of the effective date of this Section and subsequent amendments to such laws will apply to the Northern Mariana Islands, except as otherwise noted in this Covenant: (1) Those laws which provide federal services and financial assistance programs and the federal banking laws as they apply to Guam;"

Thus, under the Joint Resolution, laws which provide federal services and financial assistance apply to the Northern Mariana Islands to the same extent as they do to Guam. CMS has recognized the Joint Resolution and taken the position that the Northern Mariana Islands fall within the definition of U.S. under Medicare in 42 CFR 411.9(a). In a proposed rule published on April 25, 2006, in the

Federal Register titled "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates". (71 FR 23996), we discussed the Joint Resolution and defined the U.S. to include the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. The Northern Mariana Islands are also included in the definition of U.S. at 42 CFR 400.200. Thus, even though the Northern Mariana Islands are not explicitly referenced in sections 1861(x) and 210(h) and (i) (which notably do reference Guam) of the Act, we believe that we can consider the Northern Mariana Islands to be part of the U.S. for the purposes of the national mail order program as well.

As such, we propose to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order CBP, the fee schedule adjustment methodology under this paragraph would no longer apply. Under this proposed rule, the Northern Mariana Islands would be included in the CBA for all competitions under the national mail order CBP beginning on or after January 1, 2019.

We are soliciting comments on this proposal.

C. Provisions of the Proposed Rule

We propose to amend § 414.210(g)(7) to indicate that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.

We are soliciting comments on this proposal.

X. Request for Information on the Gap-Filling Process for Establishing Fees for New DMEPOS Items

In general, the statute mandates that fee schedule amounts established for DME, prosthetics and orthotics and other items be based on average payments made previously under the reasonable charge payment methodology. The criteria for determining reasonable charges are at 42 CFR 405.502. For example, the exclusive payment rule at sections 1834(a)(2), (3), (8), and (9) of the Act mandates that the fee schedule amounts for DME generally be based on average reasonable charges from 1986 and/or 1987, increased by annual covered item update factors. Since section 1834(a)(1)(C) of the Act mandates that

this be the exclusive payment rule for DME, as section 1834(h)(1)(D) of the Act does for prosthetic devices, prosthetics and orthotics, CMS is required to establish fee schedule amounts for these items based on the amounts and levels established under the reasonable charge payment periods set forth in the statute (that is, July 1, 1986 through June 30, 1987, for prosthetic devices, prosthetics and orthotics, therapeutic shoes, and most DME items).

Because there may be DMEPOS items that come on the market that were not paid for by Medicare during the reasonable charge payment periods that the statute mandates be used for establishing the fee schedule amounts for these items, we establish the fee schedule amounts for newly covered items using a "gap-filling" process. The gap-filling process allows Medicare to establish fee schedule amounts that align with the statutory basis for the DMEPOS fee schedule. We essentially fill the gap in the data due to the lack of historic reasonable charge payments from 1986 and 1987 by estimating what the historic reasonable charge payments would have been for the items. As described in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100-04), CMS gap-fills by using fees for comparable equipment or prices from supplier price lists, such as mail order catalogs. The gap-filling process only applies to items not assigned existing HCPCS codes that are also not items that previously were paid for under a HCPCS code that was either deleted or revised, in other words truly new items or technology as opposed to recoded/reclassified or technologically refined items or technology. This gapfilling process can result in fee schedule amounts that greatly exceed the cost to suppliers of the new technology items (such as when inflated prices from a manufacturer were used as a proxy for supplier price lists under past gapfilling exercises) or do not cover the costs of furnishing the technology if the comparable items used for gap-filling purposes are less expensive than the new item.

We are considering if changes should be made to the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. We are soliciting comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services.

XI. DMEPOS CBP Technical Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR part 414, subpart F. We propose to make two minor technical amendments to correct the existing DMEPOS CBP regulations in 42 CFR 414.422 published in the **Federal** Register on November 6, 2014, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule" (79 FR 66120) and in § 414.423 in a final rule published in the Federal Register on November 29, 2010, titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule" (75 FR 73169).

B. Proposed Technical Amendments

We are proposing to make minor technical amendments as follows:

- In § 414.422, we propose to correct the numbering in section (d)(4), which contains subsections (i) through (vi), but omits (ii) in the numbering sequence. This error was made when the regulation was promulgated. The proposed new numbering in section (d)(4) contains subsections (i) through (v), including (ii). The content of (d)(4) would remain the same.
- In § 414.423(i)(8), we propose removing the reference to "42 U.S.C." before Title 18. This statutory citation was inadvertently included when the regulation was promulgated.

regulation was promulgated.
We solicit public comments on these technical amendments and request that when commenting on this section, commenters reference "DMEPOS CBP Proposed Technical Amendments."

XII. Burden Reduction on Comorbidities

A. Background

In the CY 2011 ESRD PPS final rule (75 FR 49094), we finalized six comorbidity categories that are eligible for a comorbidity payment adjustment, each with associated International Classification of Diseases (ICD) Clinical Modification diagnosis codes (75 FR 49100). Beginning January 1, 2011, these categories included three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and

gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic anemia (including sickle cell anemia), myelodysplastic syndrome, and monoclonal gammopathy).

We stated in the same rule (75 FR 49099) that we would require ESRD facilities to have documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria that we issued in sub-regulatory guidance, specifically the Medicare Benefit Policy Manual, Pub. 100-02, Chapter 11, Section 60.A.5 (https:// www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ downloads/bp102c11.pdf). For example, to qualify for the pericarditis comorbidity adjustment, at least two of the four following criteria must be met: Atypical chest pain; pericardial friction rub; suggestive electrocardiogram changes (for example, widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported; and new or worsening pericardial effusion. In response to such requirements, stakeholders have suggested it would require additional testing or procedures to document a comorbidity, which was not our intent. Rather, our assumption was that the patient's diagnosing physician would provide the documentation. In the CY 2011 ESRD PPS final rule (75 FR 49104), we stated that ESRD facilities will obtain diagnostic information through increased communication with their patients, their patient's nephrologists and their patient's families. If there is no documentation in the medical record. the ESRD facility would be unable to claim a comorbidity payment adjustment for that patient, but could seek payment through the outlier mechanism.

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD-9-CM codes eligible for the comorbidity payment adjustment are subject to the annual ICD-9-CM coding updates that occur in the hospital Inpatient Prospective Payment System final rule and are effective October 1st of each year. We explained that any updates to the ICD-9-CM codes that affect the categories of comorbidities and the diagnoses within the comorbidity categories that are eligible for a comorbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance. We update the list of eligible diagnosis codes on an annual basis and communicate these changes through the CMS.gov website.

In the CY 2016 ESRD PPS final rule (80 FR 68989 through 68990), in consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, we finalized the elimination of the casemix payment adjustment for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy beginning in CY 2016.

B. Proposed Documentation Requirements

In the CY 2018 ESRD PPS proposed rule (82 FR 31224), we published a request for information (RFI) related to improvements to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families and invited the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. The aim of the RFI was to request information that would lead to increased quality of care, lower costs, improved program integrity, and to make the health care system more effective, simple and accessible.

After a review of the comments received in response to the RFI, we have determined that the documentation requirements associated with the conditions that are eligible for the comorbidity payment adjustment should be revisited. We have heard from stakeholders that they continue to face challenges in obtaining the required documentation in order to report specific diagnosis codes and obtain the comorbidity payment adjustments. Additionally, we have determined that the ESRD PPS documentation requirements are more rigorous than the documentation requirements under other CMS payment systems that generally rely on the ICD Official Guidelines.

In order to reduce burden on ESRD facilities and provide consistent policy across Medicare payment systems, we are proposing to reduce the documentation requirements necessary for justification of the comorbidity payment adjustment. Specifically, we would no longer require that ESRD facilities obtain results from specific diagnostic tests in order to qualify for a comorbidity payment adjustment. Instead, we propose to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. This proposal does not preclude the requirement for ESRD facilities to maintain clear documentation in the beneficiary's medical record used to justify the

reporting of diagnosis codes, which is also necessary for adherence to ICD Guidelines. Documentation required to meet ICD guidelines continues to be required for purposes of the adjustment.

We are soliciting comment on this proposal.

XIII. Requests for Information

This section addresses two requests for information (RFIs). Upon reviewing the RFIs, respondents are encouraged to provide complete, but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaidparticipating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted

electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaidparticipating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.35 While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information postdischarge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC) acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

³⁵These statistics can be accessed at: https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC ". . . for the purpose of ensuring full network-to-network exchange of health information, convene publicprivate and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." In January 2018, ONC released a draft version of its proposal for the Trusted Exchange Framework and Common Agreement,36 which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- · Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify atrisk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage

entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more

conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: Requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113-185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, longterm care hospitals (LTCHs),

rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

 Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been

clearly identified:

 Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the

time of discharge; and

 Hospitals, ČAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of

care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised

³⁶ The draft version of the trusted Exchange Framework may be accessed at: https:// beta.healthit.gov/topic/interoperability/trustedexchange-framework-and-common-agreement.

the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another communitybased provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
 Special instructions or precaution
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/ CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right

- and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/ RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104–91), and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/ RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/ resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange

- requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicaré beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete

medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and postacute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548-49) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumerfriendly way, as we previously have done by posting hospital and physician charge information on the CMS website.37 In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH

PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating our guidelines to require hospitals to make available a list of their current standard charges via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers of healthcare services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or by fees for provider and supplier services that the beneficiary considered to be part of an episode of care involving a hospital but were not services furnished by the hospital. We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers and suppliers, including services that could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers, including ESRD facilities and DME suppliers, on the following:

- How should we define "standard charges" in various provider and supplier settings? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should "standard charges" be defined to mean: Average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the provider or supplier based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a provider's or supplier's standard charges its chargemaster, price list or charge list?
- What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?
- Should providers and suppliers be required to inform patients how much their out of pocket costs for a service will be before those patients are furnished that service? How can

³⁷ See, for example, Medicare Provider Utilization and Payment Data, available at: https:// www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.

information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how copayment and coinsurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should providers and suppliers play any role in helping to inform patients of what their out-of-pocket obligations will be?

• Can we require providers and suppliers to provide patients with information on what Medicare pays for a particular service performed by that provider or supplier? If so, what changes would need to be made by providers and suppliers? What burden would be added as a result of such a

requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

 How does Medigap coverage affect patients' understanding of their out of pocket costs before they receive care? What challenges do providers and suppliers face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support providers and suppliers that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-ofpocket costs prior to receipt of care?

XIV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection requirement 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.

B. Requirements in Regulation Text

In section II.B.1 and II.B.2.b of this proposed rule, we are proposing changes to regulatory text for the ESRD PPS in CY 2019. However, the changes that are being proposed do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This proposed rule does not impose any new information collection requirements in the regulation text, as specified above. However, there are changes in some currently approved information collections. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data,38 are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purposes of the data validation studies rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.39 The mean hourly wage of a Medical Records and Health Information Technician is \$20.59 per hour. Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an hourly labor cost of \$41.18 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS

department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used these updated wage estimates along with updated facility counts and patient counts to re-estimate the total information collection burden under the ESRD QIP. We estimate the total information collection burden for the PY 2021 ESRD QIP to be \$181 million, and for PY 2022, to be \$202 million for a net incremental burden of \$21 million.

a. Estimated Time Required To Submit Data Based on Proposed Reporting Requirements

In the CY 2016 ESRD PPS final rule (80 FR 69070), we estimated that the time required to submit measure data using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files to ensure that they meet CROWNWeb's internal data format requirements.

b. Estimated Burden Associated With the Data Validation Requirements for PY 2021 and PY 2022

Section IV.B.6 of this proposed rule outlines our data validation proposals. Specifically, for the CROWNWeb validation, we are proposing to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we would use to validate CROWNWeb data for all payment years, beginning with PY 2021. Under this methodology, 300 facilities would be selected each year to submit to CMS not more than 10 records, and we would reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it would take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities would be 750 hours (300 facilities \times 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or

³⁸ https://www.bls.gov/oes/current/oes292071.htm.

³⁹ https://www.bls.gov/oes/current/oes291141.htm.

similar administrative staff would submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year would be approximately \$30,885 (750 hours × \$41.18), or an annual total of approximately \$103 (\$30,885/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

Under the proposed continued study for validating data reported to the NHSN Dialysis Event Module, we are proposing to modify the sampling methodology finalized in the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). Under the proposed modifications, we would select 150 facilities for participation in the PY 2021 validation study and 300 facilities for participation in the PY 2022 validation study. A CMS contractor would send these facilities requests for 20 patient records for each of 2 quarters of data reported in CY 2018 (for a total of 40 patient records per facility). The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it would take each facility approximately 10 hours to comply with this requirement. If 150 facilities are asked to submit records, as proposed for PY 2021, we estimate that the total combined annual burden for these facilities would be 1,500 hours (150 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2021 would be \$61,770 $(1,500 \text{ hours} \times \$41.18)$, or a total of approximately \$412 (\$61,770/150 facilities) per facility in the sample in PY 2021. If 300 facilities are asked to submit records, as proposed for PY 2022, we estimate that the total combined annual burden for these facilities would be 3,000 hours (300 facilities \times 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff would submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2022 would be $123,540 (3,000 hours \times 1.18), or a$ total of approximately \$412 (\$123,540/ 300 facilities) per facility in the sample for PY 2022. The information collection request (OMB control number 0938-1340) will be revised and sent to OMB for approval.

2. Proposed New CROWNWeb Reporting Requirements for PY 2021, PY 2022, and PY 2024

To determine the burden associated with proposed new collection of information requirements, we look at the total number of patients nationally, the number of data elements per patientyear that the facility would be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In section IV.B.1.c of this proposed rule, we are proposing to modify our data collection requirements for PY 2021 by removing four reporting measures from the ESRD QIP measure set. These changes would result in a burden collection savings of approximately \$12 million for PY 2021 (from an estimated \$193 million in total ESRD QIP burden for PY 2021 to an estimated \$181 million). Approximately \$2 million of that reduction is attributable to the proposed removal of the Pain Assessment and Follow-Up reporting measure and the remaining \$10 million of that reduction is attributable to the proposed removal of the Serum Phosphorus reporting measure. The total reduction in burden hours is approximately 300,000 hours (from an estimated 4.7 million burden hours for PY 2021 to an estimated 4.4 million burden hours). Approximately 40,000 hours of that reduction is attributable to the proposed removal of the Pain Assessment and Follow-Up reporting measure and the remaining 260,000 hours of that reduction is attributable to the proposed removal of the Serum Phosphorus reporting measure. The proposed removal of the other two reporting measures (Healthcare Personnel Influenza Vaccination and Anemia Management) would not affect our burden calculations because data on those measures are not reported through CROWNWeb.

In section IV.C.1 of this proposed rule, we are proposing to adopt two new measures beginning with PY 2022. We estimate that the burden associated with this new data collection requirement would be approximately \$21 million, or an estimated 510,000 burden hours, and that this burden would be attributable entirely to the reporting of data on the proposed MedRec measure. Since facilities are not required to submit data to CROWNWeb for the PPPW measure, we estimate that there would be no additional burden on facilities if our

proposal to adopt the PPPW measure is finalized. We estimate that the total burden increase associated with reporting data on the two new measures proposed for PY 2022 is \$21 million. The information collection request under OMB control number 0938–1289 will be revised and sent to OMB.

In section IV.D.1 of this proposed rule, we are proposing to adopt one new measure beginning in PY 2024. We estimate that the burden associated with the proposed measure will be zero. Since facilities are not required to submit data to CROWNWeb for the SWR measure, there is no burden in connection with this measure in PY 2024.

- 3. DMEPOS Competitive Bidding Program
- a. Bidding Forms A and B

Section V.D of this proposed rule outlines our proposed changes to the DMEPOS CBP. DMEPOS suppliers submit bids in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in a CBA. CMS publishes Request for Bids instructions to describe DMEPOS CBP requirements and to instruct bidders through the bid submission process. Bids are submitted electronically via the DMEPOS Bidding System (DBidS), which is the DMEPOS CBPs' online bidding system. The bids submitted before the close of the bid window are evaluated to determine which bidders will be offered contracts. Form A collects key business information to identify a bidder, the areas and products where the bidder chooses to bid, and pertinent information to indicate whether the bidder meets all eligibility requirements. A thorough analysis is performed of all information submitted to determine that the bidder has met all requirements, including licensure, financial, and quality standards. Form B contains key bid information including the bid amount for each item, historical experience providing each item, and specific manufacturer and model information for each item. The manufacturer and model information is utilized to populate the Medicare Supplier Directory during the contract period for bidders that are awarded a contract. CMS utilizes the combined information from Forms A and B to select winning bidders and establish single payment amounts for competitively bid items and services. The previously approved information collection request is under OMB control number 0938-1016.

All bidders must submit their information and signature(s) electronically into Forms A and B using DBidS. This system allows bidders to efficiently and consistently provide the necessary information contained on Forms A and B for CMS to review. Bidders are allowed to make changes to their bids at any time prior to the close of the bid window, at which time bidders are required to complete, approve, and certify their bids. The Competitive Bidding Implementation Contractor (CBIC) will use the appropriate technology to safely obtain and secure the bidding information that is transmitted. Assistance and technical support is available to bidders throughout the competitive bidding process. Bidders will be required to submit supporting documentation such as required financial documents, proof of a bid surety bond(s), and any network agreement(s) to the CBIC.

b. Burden Estimates (Hours and Wages) for Bidding Forms A and B

Form A is used to identify the bidder. This form includes information for all locations that would be included with the bid(s). In preparation for the next round, CMS has incorporated an update to this form that would also provide new instructions in accordance with § 414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid.

We have estimated the time to obtain a bid surety bond from a surety company (including contacting the company, filling out forms, submitting forms, filing paperwork, etc.) to be 11 minutes. Additionally, we estimate that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes. The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes. Therefore, the total time to complete Form A has changed from 8 hours to 8 hours and 21 minutes. Based on the number of bidders from prior rounds of competition, we have estimated the number of respondents (bidders) to be 1,500 for the next round. Each bidder would be required to complete one Form A for each round in which it bids. We anticipate that this form would be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of \$49.70, plus fringe benefits and overhead of \$49.70, for a total of \$99.40. This wage is based on the May 2017 Occupational Employment Statistics from the Bureau of Labor Statistics, plus fringe benefits and overhead, https:// www.bls.gov/oes/current/

oes113011.htm. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate a bid. We are seeking comments on this assumption. We estimate, based on information from previous rounds of competition, the burden for each bidder to complete Form A is 8 hours and 21 minutes, and \$829.99. This estimate is based on the time it takes a bidder to develop their business strategy on which CBAs and product categories to bid; obtain their bid surety bond(s); gather the required documents; and enter and review their information.

We do not know the exact number of bidders who would bid in the next round; however, for purposes of this estimate, we would assume that the number of bidders would be roughly the same as in previous rounds of competition. We estimate there would be approximately 1,500 bidders in the next round and each bidder would complete Form A once for a total of 12,525 hours and a total cost of \$1,244,985.

Bidders will use Form B to submit bids for items included in the DMEPOS CBP. This form would be completed once for each CBA and product category combination with an estimated completion time of 3 hours. Total completion time assumes the time it takes a bidder to familiarize itself on how to complete Form B, develop its bid amount and enter the applicable information into Form B. For the next round, we do not know how many bids will be submitted; however, for purposes of this estimate, we would assume the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expect the number of hours to complete Form B to decrease from previous rounds based on the removal of the expansion plan section, as well as the proposed change in bidding methodology to move to lead item pricing as described in this proposed rule. Specifically, the expansion plan section is being removed from Form B to reduce the burden for bidders as we have learned from past rounds that this information is no longer necessary. The proposed change in bidding methodology to move to lead item pricing would require bidders to only submit a single bid for an entire product category, instead of multiple bids (which can be over 100 for some product categories). We anticipate that this form would be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of \$49.70, plus fringe benefits and

overhead of \$49.70, for a total of \$99.40. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate the bid. As a result, we estimate it would require the average bidder 105 hours to complete all 35 Form Bs with a cost of \$10,437. Assuming 1,500 bidders participate in the next round of the DMEPOS CBP, and each bidder completes 35 Form Bs, there would be estimated 52,500 Form Bs submitted taking an estimated 157,500 hours for a total estimated cost of \$15,655,500.

The information collection request associated with the DMEPOS CBP will be revised and submitted to OMB under control number 0938–1016. These requirements are not effective until approved by OMB.

XV. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XVI. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this 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), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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.

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.

We solicit comments on the regulatory impact analysis provided.

2. Statement of Need

a. ESRD PPS

This rule proposes a number of routine updates and several policy changes to the ESRD PPS in CY 2019. The proposed routine updates include the CY 2019 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to ESRD patients.

h AKI

This rule also proposes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this proposed rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule proposes to implement requirements for the ESRD QIP,

including a proposal to adopt two new measures beginning with PY 2022 and a proposal to adopt a new measure beginning with PY 2024. Failure to propose requirements for the PY 2022 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2021. In addition, proposing requirements for the PY 2022 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

d. DMEPOS

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

The proposed revisions include implementation of lead item pricing and determination of SPAs based on maximum winning bids submitted for a lead item in each product category. This rule also proposes to revise the definitions of "bid" and "composite bid" and establish a new definition for "lead item."

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

We are proposing to revise $\S414.210(g)(9)$ so that for items and services furnished in rural or noncontiguous areas with dates of service from January 1, 2019 through December 31, 2020, under part 414, subpart D the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount. We are proposing to revise § 414.210(g)(9) so that for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019 through December 31, 2020, under part 414, subpart D the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

We then propose to create a new paragraph (10) under § 414.210(g) titled, "Payment Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During Temporary Gaps in the DMEPOS Competitive Bidding Program" which has the following text underneath: "During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date."

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This proposed rule would amend our regulations at § 414.226 by revising the payment rules for oxygen and oxygen equipment and adding a new paragraph after paragraph (c) that establishes some new oxygen and oxygen equipment payment classes effective January 1, 2019. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we propose establishing two classes for portable oxygen equipment: (1) One class for portable oxygen equipment (gaseous tanks) and (2) another class for portable oxygen equipment (liquid tanks.) We are also proposing to add a class for liquid oxygen contents for prescribed flow rates greater than four liters per minute and used with portable equipment. We are also proposing a new budget neutrality offset to ensure the budget neutrality of all oxygen and oxygen equipment classes added after 2006.

iv. Payment for Multi-Function Ventilators

We are proposing to add a payment rule to § 414.222(f) for multi-function ventilators that would establish payment in accordance with section 1834(a)(3) of the Act for ventilators that also perform the functions of other items of durable medical equipment subject to payment rules under paragraphs (2), (5), and (7) of section 1834(a) of the Act.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

We propose to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.

3. Overall Impact

a. ESRD PPS

We estimate that the proposed revisions to the ESRD PPS would result in an increase of approximately \$220 million in payments to ESRD facilities in CY 2019, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index.

b. AKI

We are estimating approximately \$37.0 million that would now be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2021, we have re-estimated the costs associated with information collection requirements under the Program with updated wage estimates, facility counts, and patient counts, as well as the proposed policy changes described earlier in the preamble of this proposed rule, including the proposed measure removals. We also re-estimated the payment reductions under the ESRD QIP in accordance with the proposed policy changes described earlier, including the proposed domain restructuring and reweighting. We estimate that these updates would result in an overall impact of \$219 million associated with quality reporting burden and payment reductions, which includes a \$12 million incremental reduction in burden in collection of information requirements and \$38 million in estimated payment reductions across all facilities.

For PY 2022, we estimate that the proposed revisions to the ESRD QIP would result in an increase in overall impact to \$240 million, which includes a \$21 million incremental increase associated with the proposed collection of information requirements and \$38 million in estimated payment reductions across all facilities.

d. DMEPOS

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

This proposed rule with comment period, which proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, (which we expect could potentially be delayed until January 1, 2021) has impacts estimated by rounding to the nearer 5 million dollars and is expected to cost \$10 million in Medicare benefit payments and roughly \$3 million in Medicare beneficiary cost sharing for

the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost \$1,050 million in Medicare benefit payments and \$260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$45 million and \$30 million, respectively.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This proposed rule establishes new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule proposes to establish payment rules for multi-function ventilators. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost \$15 million in Medicare benefit payments and \$0 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be \$0 million.

v. Including the Northern Mariana Islands in Future National Mail Order CBPs

This change would not have a fiscal impact.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the BLS (https://www.bls.gov/oes/2017/may/naics4_621100.htm) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is \$110.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this proposed rule. For each ESRD facility that reviews the rule, the estimated cost is \$687.50 (6.25 hours × \$110.00). Therefore, we estimate that the total cost of reviewing this

regulation rounds to \$39,875. ($$687.50 \times 58$ reviewers).

For DME suppliers, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review this proposed rule. For each entity that reviews this proposed rule, the estimated cost is \$220.00 (2 hours \times \$110.00). Therefore, we estimate that the total cost of reviewing this proposed rule is \$143,000 (\$220.00 \times 650 reviewers).

- B. Detailed Economic Analysis
- 1. CY 2019 End-Stage Renal Disease Prospective Payment System
- a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only

for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of February 16, 2018, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the ESRD PPS base rate are described in section II.B.3.h of this proposed rule. Table 58 shows the impact of the estimated CY 2019 ESRD payments compared to estimated payments to ESRD facilities in CY 2018.

TABLE 58—IMPACT OF PROPOSED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2019 PROPOSED RULE

| Facility type | Number of facilities | Number of treatments (in millions) | Effect of 2019 changes in outlier policy (%) | Effect of 2019 changes in wage index, wage floor, and labor- related share (%) | Effect of 2019 changes in payment rate update (%) | Effect of total 2019 proposed changes (outlier, wage index and floor, labor- related share, routine updates to the payment rate) (%) |
|---|----------------------|--|---|--|---|--|
| | Α | В | С | D | E | F |
| All FacilitiesType: | 7,042 | 44.5 | 0.2 | 0.0 | 1.5 | 1.7 |
| Freestanding | 6,626 | 42.4 | 0.2 | 0.0 | 1.5 | 1.7 |
| Hospital based Ownership Type: | 416 | 2.1 | 0.4 | -0.1 | 1.5 | 1.8 |
| Large dialysis organization | 5,355 | 34.4 | 0.2 | 0.0 | 1.5 | 1.7 |
| Regional chain | 871 | 5.7 | 0.3 | 0.1 | 1.5 | 1.9 |
| Independent | 479 | 2.9 | 0.2 | 0.2 | 1.5 | 2.0 |
| Hospital based 1 | 325 | 1.6 | 0.4 | 0.0 | 1.5 | 1.9 |
| Unknown | 12 | 0.0 | 0.1 | 0.3 | 1.5 | 1.9 |
| Geographic Location: | | | | | | |
| Rural | 1,263 | 6.4 | 0.2 | -0.3 | 1.5 | 1.4 |
| Urban Census Region: | 5,779 | 38.1 | 0.2 | 0.0 | 1.5 | 1.8 |
| East North Central | 1,136 | 6.2 | 0.2 | -0.4 | 1.5 | 1.4 |
| East South Central | 569 | 3.3 | 0.2 | -0.7 | 1.5 | 1.1 |
| Middle Atlantic | 769 | 5.4 | 0.2 | 0.1 | 1.5 | 1.8 |
| Mountain | 398 | 2.3 | 0.2 | -0.3 | 1.5 | 1.4 |
| New England | 191 | 1.5 | 0.2 | -0.3 | 1.5 | 1.4 |
| Pacific ² | 837 | 6.4 | 0.2 | 1.1 | 1.5 | 2.8 |
| Puerto Rico and Virgin Islands | 51 | 0.3 | 0.1 | 4.5 | 1.5 | 6.2 |
| South Atlantic | 1,612 | 10.4 | 0.3 | -0.3 | 1.5 | 1.5 |
| West North Central | 492 | 2.3 | 0.3 | -0.3 | 1.5 | 1.5 |
| West South Central | 987 | 6.5 | 0.2 | -0.1 | 1.5 | 1.7 |
| Facility Size: | 1.000 | | 0.0 | 0.0 | 4.5 | 4.0 |
| Less than 4,000 treatments4,000 to 9,999 treatments | 1,689 2,502 | 5.9 11.8 | 0.2 | 0.0 -0.2 | 1.5 1.5 | 1.8 |
| 10,000 or more treatments | 2,776 | 26.7 | 0.2 | 0.1 | 1.5 | 1.8 |
| Unknown | 2,776 75 | 0.2 | 0.2 | 0.1 | 1.5 | 2.2 |
| Percentage of Pediatric Patients: | /3 | 0.2 | 0.4 | 0.5 | 1.5 | |
| Less than 2% | 6,938 | 44.2 | 0.2 | 0.0 | 1.5 | 1.7 |
| Between 2% and 19% | 41 | 0.3 | 0.3 | 0.0 | 1.5 | 1.8 |
| Between 20% and 49% | 12 | 0.0 | 0.1 | -0.4 | 1.5 | 1.3 |
| More than 50% | 51 | 0.0 | 0.1 | 0.2 | 1.5 | 1.8 |

Sensipar and Parsabiv will be paid under the transitional drug add-on payment adjustment for CY 2019. In CY 2016 there was approximately \$840 million in spending for Sensipar under Part D.

³ Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

² Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the proposed changes to the outlier payment policy described in section II.B.3.g of this proposed rule is shown in column C. For CY 2019, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.2 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2019 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the proposed CY 2019 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments ranging from a -0.7 percent to a 4.5 percent increase due to these proposed updates in the wage indices.

Column E shows the effect of the proposed CY 2019 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.5 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2019 of 2.2 percent and the proposed MFP adjustment of 0.7 percent.

Column F reflects the overall impact, that is, the effects of the proposed outlier policy changes, the proposed wage index floor, and payment rate update. We expect that overall ESRD facilities would experience a 1.7 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.1 percent

to 6.2 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2019, we estimate that the proposed ESRD PPS would have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2019 would be approximately \$10.6 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 1.2 percent in CY 2019.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.7 percent overall increase in the proposed CY 2019 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 1.7 percent in CY 2019, which translates to approximately \$60 million.

e. Alternatives Considered

In section II.B.3.b of this proposed rule, we proposed changes to the wage index floor.

We considered maintaining the existing wage index floor of 0.4000 and also considered increasing the wage

floor to 0.5500 and 0.5800. However, based on the analyses we have conducted, we no longer believe a wage index floor value of 0.4000 is appropriate and we are concerned about the impact a higher floor value would have on the base rate.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals With AKI

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this proposed rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of February 16, 2018, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the AKI payment amount are described in section III.B of this proposed rule. Table 59 shows the impact of the estimated CY 2019 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2018.

TABLE 59—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS
WITH AKI FOR CY 2019 PROPOSED RULE

| Facility type | Number of facilities | Number of treatments (in thousands) | Effect of 2019 changes in wage index, wage floor, and labor-related share (%) | Effect of 2019 changes in payment rate update (%) | Effect of total 2019 proposed changes (%) |
|-----------------------------|----------------------|---|--|---|---|
| | (A) | (B) | (C) | (D) | (E) |
| All Facilities | 3,861 | 156.9 | 0.0 | 1.5 | 1.5 |
| Freestanding | 3,775 | 153.7 | 0.0 | 1.5 | 1.5 |
| Hospital based | 86 | 3.2 | -0.1 | 1.5 | 1.4 |
| Ownership Type | | | | | |
| Large dialysis organization | 3,269 | 134.8 | 0.0 | 1.5 | 1.5 |
| Regional chain | 416 | 15.1 | 0.0 | 1.5 | 1.5 |
| Independent | 119 | 4.5 | 0.1 | 1.5 | 1.6 |
| Hospital based 1 | 55 | 2.5 | 0.0 | 1.5 | 1.5 |
| Unknown | 2 | 0.0 | -0.3 | 1.5 | 1.2 |
| Geographic Location | | | | | |
| Rural | 691 | 25.7 | -0.2 | 1.5 | 1.3 |

TABLE 59—IMPACT OF PROPOSED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2019 PROPOSED RULE—Continued

| Facility type | Number of facilities | Number of treatments (in thousands) | Effect of 2019 changes in wage index, wage floor, and labor-related share (%) | Effect of 2019 changes in payment rate update (%) | Effect of total 2019 proposed changes (%) |
|----------------------------------|----------------------|---|--|---|---|
| | (A) | (B) | (C) | (D) | (E) |
| Urban Census Region | 3,170 | 131.2 | 0.1 | 1.5 | 1.6 |
| East North Central | 706 | 29.9 | -0.3 | 1.5 | 1.2 |
| East South Central | 310 | 10.5 | -0.6 | 1.5 | 0.9 |
| Middle Atlantic | 401 | 16.5 | 0.0 | 1.5 | 1.5 |
| Mountain | 244 | 11.0 | -0.2 | 1.5 | 1.3 |
| New England | 123 | 4.7 | -0.4 | 1.5 | 1.1 |
| Pacific ² | 482 | 27.0 | 1.1 | 1.5 | 2.7 |
| Puerto Rico and Virgin Islands | 2 | 0.0 | 6.0 | 1.5 | 7.6 |
| South Atlantic | 872 | 34.1 | -0.3 | 1.5 | 1.2 |
| West North Central | 251 | 7.7 | -0.2 | 1.5 | 1.3 |
| West South Central | 470 | 15.6 | -0.2 | 1.5 | 1.3 |
| Facility Size | | | | | |
| Less than 4,000 treatments | 720 | 25.5 | 0.2 | 1.5 | 1.7 |
| 4,000 to 9,999 treatments | 1,403 | 51.4 | -0.2 | 1.5 | 1.3 |
| 10,000 or more treatments | 1,716 | 79.1 | 0.1 | 1.5 | 1.6 |
| Unknown | 22 | 1.0 | 0.3 | 1.5 | 1.8 |
| Percentage of Pediatric Patients | | | | | |
| Less than 2% | 3,860 | 156.7 | 0.0 | 1.5 | 1.5 |
| Between 2% and 19% | 1 | 0.2 | 0.6 | 1.5 | 2.1 |
| Between 20% and 49% | 0 | 0.0 | 0.0 | 0.0 | 0.0 |
| More than 50% | 0 | 0.0 | 0.0 | 0.0 | 0.0 |

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the proposed CY 2019 wage indices and the wage index floor of 0.50. The categories of types of facilities in the impact table show changes in estimated payments of a 1.5 percent increase due to these proposed updates in the wage indices.

Column D shows the effect of the proposed CY 2019 ESRD PPS payment rate update. The proposed ESRD PPS payment rate update is 1.5 percent, which reflects the proposed ESRDB market basket percentage increase factor for CY 2019 of 2.2 percent and the MFP adjustment of 0.7 percent.

Column E reflects the overall impact, that is, the effects of the proposed wage index floor and payment rate update. We expect that overall ESRD facilities would experience a 1.5 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 7.6 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are

proposing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately \$30.0 million would be paid to ESRD facilities in CY 2019 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients would continue to be

responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we would expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS casemix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The methodology that we are proposing to use to determine a facility's TPS for the PY 2022 ESRD QIP is described in

section IV.C of this proposed rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP would apply to ESRD PPS payments made to the facility for services furnished in CY 2022.

For the PY 2022 ESRD QIP, we estimate that, of the 6,814 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 44.31 percent or 2,896 of

the facilities would receive a payment reduction for PY 2022. The total payment reduction for all of the 2,896 facilities expected to receive a reduction is approximately \$38,114,871.88. Facilities that do not receive a TPS do not receive a payment reduction.

Table 60 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 60—ESTIMATED DISTRIBUTION OF PY 2022 ESRD QIP PAYMENT REDUCTIONS

| Payment reduction | Number of facilities | Percent of facilities |
|-------------------|----------------------|-----------------------|
| 0.0% 0.5% | 3,639 | 55.68 20.67 |
| 1.0% | 1,351 923 | 14.12 |
| 1.5% | 437 | 6.69 |
| 2.0% | 185 | 2.83 |

Note: This table excludes 279 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a TPS.

To estimate whether a facility would receive a payment reduction in PY 2022, we scored each facility on achievement

and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 61.

TABLE 61—DATA USED TO ESTIMATE PY 2022 ESRD QIP PAYMENT REDUCTIONS

| Measure | Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds | Performance period |
|--|--|--|
| VAT: Standardized Fistula Rate Long Term Catheter Rate Kt/V Dialysis Adequacy Comprehensive Hypercalcemia STrR ICH CAHPS Survey SRR NHSN BSI SHR | Jan 2015–Dec 2015 | Jan 2016-Dec 2016. Jan 2016-Dec 2016. |

For all measures except STrR and SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPŠ. For SHR and STrR, facilities were required to have at least 5 and 10 patient-years at risk, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B.3.b of this proposed rule. Facility reporting measure scores were estimated using available data from CY 2015 and 2016. Facilities were required to have a score

on at least one clinical measure to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this proposed rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2016 and December 2016 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2016 through December 2016 times the estimated payment reduction percentage.

Table 62 shows the estimated impact of the finalized ESRD QIP payment

reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the performance periods used for these calculations will differ from those we propose to use for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may vary significantly from the values provided here.

TABLE 62—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2022

| | Number of facilities | Number of treatments 2016 (in millions) | Number of facilities with QIP score | Number of facilities expected to receive a payment reduction | Payment reduction (percent change in total ESRD payments) |
|---|----------------------|--|--|--|---|
| All Facilities | 6,814 | 45.1 | 6,535 | 2,896 | -0.40 |
| Facility Type: | | | | | |
| Freestanding | 6,383 | 42.7 | 6,149 | 2,740 | -0.40 |
| Hospital-based | 431 | 2.4 | 386 | 156 | -0.39 |
| Ownership Type: | | | | | |
| Large Dialysis | 5,110 | 34.3 | 4,945 | 2,131 | -0.37 |
| Regional Chain | 871 | 5.8 | 841 | 341 | -0.36 |
| Independent | 487 | 3.1 | 448 | 291 | -0.69 |
| Hospital-based (non-chain) | 341 | 1.8 | 301 | 133 | -0.44 |
| Unknown | 5 | 0.0 | 0 | 0 | |
| Facility Size: | | | | | |
| Large Entities | 5,981 | 40.1 | 5,786 | 2,472 | -0.37 |
| Small Entities ¹ | 828 | 5.0 | 749 | 424 | -0.59 |
| Unknown | 5 | 0.0 | 0 | 0 | |
| Rural Status: | | | | | |
| (1) Yes | 1,243 | 6.5 | 1,212 | 380 | -0.25 |
| (2) No | 5,571 | 38.6 | 5,323 | 2,516 | -0.43 |
| Census Region: | | | | | |
| Northeast | 933 | 7.0 | 894 | 462 | -0.48 |
| Midwest | 1,593 | 8.6 | 1,504 | 538 | -0.30 |
| South | 3,048 | 20.4 | 2,929 | 1,463 | -0.45 |
| West | 1,183 | 8.6 | 1,151 | 389 | -0.28 |
| U.S. Territories ² | 57 | 0.4 | 57 | 44 | -0.99 |
| Census Division: | _ | | - | | 0.57 |
| Unknown | 7 | 0.1 | 1.007 | 4 | -0.57 |
| East North Central | 1,109 | 6.4 3.4 | 1,037 534 | 403 244 | - 0.34 - 0.41 |
| East South Central Middle Atlantic | 551 742 | 5.5 | 710 | 390 | - 0.41 - 0.52 |
| Mountain | 382 | 2.2 | 370 | 390 82 | -0.52 -0.17 |
| New England | 191 | 1.5 | 184 | 72 | -0.17 -0.30 |
| Pacific Pacific | 801 | 6.3 | 781 | 307 | -0.30 -0.34 |
| South Atlantic | 1.572 | 10.5 | 1,498 | 774 | -0.34 -0.47 |
| West North Central | 484 | 2.3 | 467 | 135 | -0.47 -0.22 |
| West South Central | 925 | 6.5 | 897 | 445 | - 0.22 - 0.45 |
| U.S. Territories 2 | 50 | 0.4 | 50 | 40 | - 1.05 |
| Facility Size (number of total treatments): | 30 | 0.4 | 30 | 40 | - 1.03 |
| Less than 4,000 treatments | 1.127 | 2.0 | 900 | 301 | -0.33 |
| 4,000–9,999 treatments | 2,514 | 11.6 | 2,502 | 978 | - 0.35 - 0.35 |
| Over 10,000 treatments | 3,007 | 30.6 | 3,007 | 1,558 | - 0.45 |
| Unknown | 166 | 0.9 | 126 | 59 | - 0.50 |

¹ Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.

b. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other outpatient facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to

continue examining the interactions between our quality programs to the greatest extent feasible.

c. Effects on the Medicare Program

For PY 2022, we estimate that ESRD QIP would contribute approximately \$38,114,872 in Medicare savings. For comparison, Table 63 shows the payment reductions that we estimate will be achieved by the ESRD QIP from PY 2017 through PY 2022.

TABLE 63—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEAR 2017 THROUGH 2022

| Payment year | Estimated payment reductions (citation) | |
|--------------|---|--|
| PY 2022 | \$38,114,872. | |

TABLE 63—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEAR 2017
THROUGH 2022—Continued

| Payment year | Estimated payment reductions (citation) |
|--------------|---|
| PY 2021 | \$37,872,521. |
| PY 2020 | \$31,581,441 (81 FR 77960). |
| PY 2019 | \$15,470,309 (80 FR 69074). |
| PY 2018 | \$11,576,214 (79 FR 66257). |
| PY 2017 | \$11,954,631 (79 FR 66255). |

Additionally, we estimate that the proposed removal of four reporting measures beginning with PY 2021 would reduce the information collection burden by \$12 million.

d. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's

² Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. To date we have been unable to examine the impact of the ESRD QIP on Medicare beneficiaries including the financial impact of the Program or the impact on the health outcomes of beneficiaries. However, in future years we are interested in examining these impacts through the addition of new measures to the Program and through the analysis of available data from our existing measures.

Additionally, in this proposed rule, we are proposing changes to the ESRD QIP to reflect the Meaningful Measures Initiative's priorities, including focusing our quality measure set on more outcome-oriented, less burdensome quality measures. We believe that the changes we are proposing, which include a reduced information collection burden of \$12 million for PY 2021, will help focus the Program's measurements on the most clinically appropriate topics while ensuring that facilities are not unduly burdened by quality reporting requirements.

e. Alternatives Considered

As discussed in section IV.B.3.b of this proposed rule, we considered two alternatives for reassigning measure weights in situations where a facility does not receive a score on at least one measure but is still eligible to receive a TPS score: (1) Redistribute the weight of missing measures evenly across the remaining measures (that is, we would divide up the missing measure's weight equally across the remaining measures), and (2) redistribute the weight of missing measures proportionately across the remaining measures, based on their weight as a percentage of TPS (that is, when dividing up a missing measure's weight, we would shift a larger share of that weight to measures with a higher assigned weight; measures with a lower weight would gain a smaller portion of the missing measure's weight).

While the first policy alternative is administratively simpler to implement, we rejected this option because it would not maintain the Meaningful Measure Initiative priorities in the measure weights as effectively as the second policy alternative. In section IV.B.3 of this proposed rule, we propose an approach for reweighting the domains and measures in the ESRD QIP in PY 2021 based on the priorities identified in the Meaningful Measures Initiative. For example, we propose to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. If we adopted the first policy alternative, measures that we consider a lower priority would represent a much larger share of TPS relative to measures that we consider a higher priority, in situations where a facility is missing one or more measure scores. Under the second policy alternative, when a facility is not scored on a measure, the weight of lower priority measures relative to higher priority measures would be more consistent with the weights assigned to the complete measure set. For example, if a facility was ineligible to receive a score on all the measures in both the Clinical Care Measure Domain and the Safety Measure Domain in PY 2022, the weight of the Clinical Depression and Follow-Up Measure—the lowest weight remaining in the measure set would increase from 2.5 percent of the TPS to 13.5 percent of the TPS under the first policy alternative and would increase from 2.5 percent of the TPS to 5.6 percent of the TPS under the second policy alternative. Under the same scenario, the weight of the ICH CAHPS measure—the highest weight remaining in the measure set would increase from 15 percent to 26 percent under the first policy alternative and would increase from 15 percent to 33.33 percent under the second policy alternative.

4. DMEPOS

a. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

i. Effects on Other Providers

We believe that using the maximum winning bid amount and lead item pricing to establish the SPAs and paying most contract suppliers more than they bid helps to ensure beneficiary access to DMEPOS and long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Further, lead item pricing simplifies the supplier's bidding process. We anticipate that more suppliers would compete given the simpler rules and the fact that all winning bidders would be paid at least as much as they bid. Therefore, we

believe that this proposal would have a positive economic impact on bidding suppliers.

ii. Effects on the Medicare Program

This proposed rule, which proposes to base single payment amounts on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, is estimated by rounding to the nearer 5 million dollars and is expected to cost \$10 million in Medicare benefit payments for the 5year period beginning January 1, 2019 and ending September 30, 2023. The estimate uses the current baseline which bases the SPAs on the median of winning bids. The cost of the proposal is the sum of yearly impacts. Each year's impact is the product of the projected spending on items subject to competitive bidding furnished in former CBAs for that year multiplied by the percentage increase in aggregate spending due to the change in the payment rules, in this case 0.2 percent.

In considering a future in which the current regulations remain in place (the regulatory baseline), we note that over the long run, a potential supplier would be motivated to continue bidding if its expenses are below its expectation for the median of the winning bids. As such, this long run—in which suppliers have learned the likely bidding outcomes—could result in no contracts or payments at SPA levels set too low to ensure access. In this scenario, bidders might have minimal incentive to change their bidding behavior based upon a policy switch from median to maximum winning bid to determine SPAs. After all, the baseline pricing method would award contracts to the suppliers with bids below the median at prices that at least cover their production costs. Additionally, it is possible that the behavioral response of bidders who, knowing that the SPA would be set based on the maximum winning bid, would respond by bidding more competitively in a CBP round where the payment is determined based on the maximum winning bid. The trade-off between setting the SPA using the maximum winning bid and the fact that bids are more competitive, hence lowering costs, tend to balance one another out so that the resulting SPAs would be expected to be similar to the SPAs set using median bid. This tradeoff is termed Revenue Equivalency with the expected result being that bidders would respond in a manner that would mitigate the SPA determination methodology change to maximum winning bid. In other words, a relatively low impact, such as that presented in

this section, could be reasonable considering Revenue Equivalency.

As noted earlier in the preamble, median bid levels have trended lower with each successive round of competition. To the extent that factors impacting the competition are still developing, the impacts of this policy proposal may be underestimated. We request comment that would allow for refinement of the impact estimate for the final rule. We also seek comment and information on how much DMEPOS production costs change from year to year; whether the changes likely to be common across suppliers, or at least well known amongst them. We would also seek comment and information on the duration of time the bidding process requires to reach steady participation so that payment outcomes occur due to the implementation of new policies for the subsequent rounds of CBP (such as the surety bond policy that was part of the 2016 ESRD PPS final rule).

iii. Effects on Medicare Beneficiaries

This proposed rule would base single payment amounts on the maximum winning bid and implement lead item pricing in the Medicare DMEPOS CBP. The effects are estimated by rounding to the nearer 5 million dollars and to cost roughly \$3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019 and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$0 million. Section 503 of the Consolidated Appropriations Act of 2016 and section 5002 of the Cures Act, added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. Many states have started limiting payment for DME based on the Medicare rates, but the majority of the states do not currently have the ability to use rates that apply to only parts of the state, such as rates paid in CBAs or rural areas of the state.

iv. Alternatives Considered

One alternative we considered was to continue the Medicare DMEPOS CBP with no changes. This would have no economic impact on the Medicare program or its beneficiaries.

Another alternative is to implement lead item pricing based on maximum winning bids as proposed, but offer contracts based on overall demand for items and services and unadjusted supplier capacity. We believe that currently more contracts are offered under the program than are needed to meet overall demand for items and services, so this is potentially an option we could consider. For example, we currently limit a supplier's capacity to 20 percent of projected demand. We could eliminate this limit which could result in less winning contracts being offered. However, the risk is that the number of contract suppliers could be reduced too much and could lead to access problems.

b. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

In the event of a gap in the CBP beginning January 1, 2019, any enrolled supplier can furnish the items currently subject to competitive bidding in former CBAs and non-CBAs. The suppliers furnishing items in former CBAs would be paid slightly more than the current SPAs based on the median of winning bids because the proposed fee schedule adjustment methodology for items and services furnished in former CBAs would adjust the fee schedule amounts for such items and services based on the current SPAs plus a CPI-U update. We understand this proposal to be consistent with the requirements of section 1834(a)(1)(F) of the Act. The suppliers furnishing items in non-CBAs would be paid based on current fee schedule amounts.

i. Effects on the Medicare Program

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 for areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or noncontiguous areas. The impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs

are done consistent with the rules in place as of January 1, 2018. The impacts are expected to cost \$1,050 million dollars in Medicare benefit payments for the 2-year period beginning January 1, 2019 and ending December 31, 2020.

ii. Effects on Medicare Beneficiaries

This rule proposes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019 in areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule proposes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019, through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or noncontiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018. The impacts are expected to cost \$265 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be \$45 million and \$30 million, respectively.

iii. Alternatives Considered

One alternative we considered but did not propose was to establish a fee schedule adjustment methodology that uses the blended (75 unadjusted/25 adjusted) rates in all super rural and non-contiguous areas, and the blended (25 unadjusted/75 adjusted) rates in all other non-CBAs. In this alternative, the fee schedule amount for items furnished in current CBAs would be based on the current SPAs updated by the projected change in the CPI-U. This alternative is estimated by rounding to the nearer 5 million dollars and is expected to cost \$30 million in Medicare benefit payments and \$5 million in Medicare beneficiary cost sharing beginning

January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$0 million and \$0 million, respectively.

Another alternative we considered but did not propose was to maintain the current SPA determination methodology, which bases the SPA on the median of winning bids, for the CBAs and maintain the current fee schedule adjustment methodologies for the non-CBAs. This alternative is estimated by rounding to the nearer 5 million dollars and to save \$1,140 million in Medicare benefit payments and \$280 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be \$50 million and \$40 million, respectively.

We request public comments on these alternatives.

c. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

i. Effects on Other Providers

Suppliers of high-flow oxygen equipment and oxygen contents would get paid more when furnishing oxygen to the high-risk beneficiaries who have been prescribed high-flow oxygen. The budget neutrality offset applied to all oxygen classes would lessen the offset applied to the stationary oxygen equipment fee schedule amount, which would be to the advantage of suppliers that furnish only stationary oxygen equipment.

ii. Effects on the Medicare Program

No fiscal impact due to the annual budget neutrality calculation.

iii. Effects on Medicare Beneficiaries

No fiscal impact due to the annual budget neutrality calculation.

iv. Alternatives Considered

One alternative we considered but did not propose was to apply the budget neutrality offset to all DME, not just to the oxygen classes as proposed. This would have no fiscal impact because it would be budget neutral.

Another alternative we considered but did not propose was to eliminate OGPE classes added in 2006 and resort back to modality neutral payments for both stationary and portable equipment. This alternative would have no fiscal impact, either.

d. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

i. Effects on Other Providers

Suppliers of high-flow oxygen equipment and oxygen contents would get paid more when furnishing oxygen to the high-risk beneficiaries who have been prescribed high-flow oxygen. The budget neutrality offset applied to all oxygen classes would lessen the offset applied to the stationary oxygen equipment fee schedule amount, which would be to the advantage of suppliers that furnish only stationary oxygen equipment.

ii. Effects on the Medicare Program

No fiscal impact due to the annual budget neutrality calculation.

iii. Effects on Medicare Beneficiaries

No fiscal impact due to the annual budget neutrality calculation.

iv. Alternatives Considered

One alternative we considered but did not propose was to apply the budget neutrality offset to all DME, not just to the oxygen classes as proposed. This would have no fiscal impact because it would be budget neutral.

Another alternative we considered but did not propose was to eliminate OGPE classes added in 2006 and resort back to modality neutral payments for both stationary and portable equipment. This alternative would have no fiscal impact, either

e. Payment for Multi-Function Ventilators

i. Effects on Other Providers

We expect that the impact of our proposal to classify the multi-function ventilator item in the frequent and substantial servicing payment category and our proposed payment rule for determining the monthly rental fee schedule amount would overall result in a slight increase in payments to suppliers since the suppliers would continue to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions. In addition, the supplier would retain ownership of the multi-function ventilator that is used and can furnish the equipment for additional separate rental periods to other beneficiaries.

ii. Effects on the Medicare Program

We expect our proposed payment rule for multi-function ventilators to be a 5-

year cost of \$15 million to the Medicare program as the proposed payment method would result in suppliers continuing to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions.

iii. Effects on Medicare Beneficiaries

We expect the proposal would have a negligible effect on Medicare beneficiaries' copayments.

iv. Alternatives Considered

We considered two alternatives for our proposed payment rule for multifunction ventilators. One alternative payment approach is to pay a ventilator base item monthly rental amount and also pay separate, add-on monthly rental payments for each of the four additional functions of the item. This alternative is expected to have no cost to the beneficiaries or the Medicare program. Another alternative payment approach is to establish a monthly rental payment amount for a ventilator plus the monthly cost of all four additional functions. However, this payment alternative would only be allowed if the patient requires all five functions of the multi-function ventilator. This alternative is expected to have no cost to the beneficiaries or the Medicare program. Each of these alternatives did not approach the new multi-function ventilator as an integrated item that encompasses efficiencies for the suppliers, beneficiaries and the program. Also, neither of these two alternatives would address payment for multi-function ventilators in a different manner than paying for five separate items that perform the same functions. Thus, we did not elect to pursue these alternatives.

f. Including the Northern Mariana Islands in Future National Mail Order CBPs

Because this proposal would not have a fiscal impact, no detailed economic analysis is necessary.

C. Accounting Statement

As required by OMB Circular A–4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 64, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of this proposed rule.

| 34408 Federal Register/Vol. 83, No. 139/Tl | | - | | |
|---|--|---|---------------------|--------------------|
| TABLE 64—ACCOUNTING STATEMENT: CLASSIFICAT ESRD PP | ION OF ESTIMAT S and AKI | ED TRANSFERS | AND COSTS/SA | VINGS |
| Category | | Tran | sfers | |
| Annualized Monetized Transfers | \$190 million. Federal government to ESRD providers. | | | |
| Category | | Tran | sfers | |
| Increased Beneficiary Co-insurance Payments | \$30 million. Beneficiaries to ESRD providers. | | | |
| ESRD QIP | for PY 2021 | | | |
| Category | | Tran | sfers | |
| Annualized Monetized Transfers | -\$38 million. Federal government to ESRD providers. | | | |
| Category | | Co | ests | |
| Annualized Monetized ESRD Provider Costs | \$181 million. The PY 2021 policy changes would result in an estimated \$12 mill in savings. | | | mated \$12 millior |
| ESRD QIP | for PY 2022 | | | |
| Category | | Tran | sfers | |
| Annualized Monetized Transfers | -\$38 million. Federal government to ESRD providers. | | | |
| Category | Costs | | | |
| Annualized Monetized ESRD Provider Costs | \$202 million. The PY 2022 policy changes would result in an estimated \$21 mill increase. | | | mated \$21 millior |
| DME Provisions: Competitive Bidding Re | eforms Annualizatio | n Period 2019 to 2 | 2023 | |
| | | Transfers | | |
| Category | | Estimates | Year dollar | Discount rate |
| Annualized Monetized Transfer on Beneficiary Cost Sharing (in \$Millions) | | \$2 \$2 | 2019 2019 | 7% 3% |
| From Whom to Whom | | Beneficiaries to Medicare providers | | |
| | | | Transfers | |
| | | Estimates | Year dollar | Discount rate |
| Annualized Monetized Transfer Payments (in \$Millions) | | \$0.6 \$0.6 | 2019 2019 | 7% 3% |
| From Whom to Whom | | Federal government to Medicare providers. | | |
| DME Provisions: Transitional Fee Adjus | tments Annualizatio | n Period 2019 to 2 | 2020 | |
| Category | | Transfers | | |
| | | Estimates | Year dollar | Discount rate |
| Annualized Monetized Transfer on Beneficiary Cost Sharing (in \$Millions) | | \$506 \$516 | 2019 2019 | 7% 3% |
| From Whom to Whom | | Beneficia | aries to Medicare p | oroviders. |
| | | | Transfers | |
| | | Estimates | Year dollar | Discount rate |
| Annualized Monetized Transfer Payments (in \$Millions) | | \$128 \$130 | 2019 2019 | 7% 3% |

Federal government to Medicare providers.

From Whom to Whom

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

XVII. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96-354) (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. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than \$38.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's Web site at http://www.sba.gov/content/smallbusiness-size-standards (Kidney Dialysis Centers are listed as 621492 with a size standard of \$38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and States are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 58. Using the definitions in this ownership category, we consider 479 facilities that are independent and 325 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than \$38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates proposed in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.9 percent increase in payments for CY 2019. An independent facility (as defined by ownership type) is also estimated to receive a 2.0 percent increase in payments for CY 2019.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for \$37.5 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For ESRD QIP, we estimate that of the 2,896 ESRD facilities expected to receive a payment reduction in the PY 2022 ESRD QIP, 424 are ESRD small entity facilities. We present these findings in Table 60 ("Estimated Distribution of PY 2022 ESRD QIP Payment Reductions") and Table 61 ("Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2022"). We estimate that the payment reductions would average approximately \$13,161 per facility across the 2,896 facilities receiving a payment reduction, and \$14,665 for each small entity facility. We also estimate that there are 828 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities would decrease 0.59 percent in PY 2022.

For DMEPOS, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration's size standards with total revenues of \$6.5million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. As discussed in section VI of this proposed rule, this rule would provide additional revenue to a substantial number of small rural entities, especially for certain items furnished outside of the former competitively bid areas. Therefore, the Secretary has determined that these proposed rules would have a significant economic impact on a substantial number of small entities.

Therefore, the Secretary has determined that these proposed rules would have a significant economic impact on a substantial number of small entities. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically "significant" only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We solicit comment on the RFA analysis provided.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Any such regulatory impact analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this proposed rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 132 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 132 rural hospital-based dialysis facilities will experience an estimated 1.6 percent increase in payments. As concerns the DME parts of the rule, our data indicates that only around 6.9 percent of small rural hospitals are organizationally linked to a DME supplier with paid claims in 2017. Thus, we do not believe the DME parts of the rule will have a significant impact on operations of a substantial number of small rural hospitals. As a result, the entire proposed rule is not estimated to have a significant impact on small rural hospitals.

Therefore, the Secretary has determined that these proposed rules would not have a significant impact on the operations of a substantial number of small rural hospitals.

XVIII. Unfunded Mandates Reform Act Analysis

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 2018, that threshold is approximately \$150 million. These proposed rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of \$150 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

XIX. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed these proposed rules under the threshold criteria of Executive Order 13132. Federalism, and have determined that it would have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments. It is estimated that these proposals contained in section VI of this proposed rule would add \$30 million dollars of additional expense to state governments because of the added cost sharing expense for Medicare and Medicaid dual eligible beneficiaries.

XX. Reducing Regulation and **Controlling Regulatory Costs**

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This proposed rule is expected to be an Executive Order 13771 regulatory action due to the estimated \$9 million incremental costs (see Table 64).

XXI. Congressional Review Act

These proposed 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.) and has been transmitted to the Congress and the Comptroller General for review.

XXII. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rulemakings will no longer appear in the Federal Register. Instead, the Addenda will be available only through the Internet and is posted on the CMS website at http:// www.cms.gov/ESRDPayment/PAY/ list.asp. In addition to the Addenda, limited data set (LDS) files are available for purchase at http://www.cms.gov/ Research-Statistics-Data-and-Systems/ Files-for-Order/LimitedDataSets/ EndStageRenalDiseaseSystemFile.html. Readers who experience any problems accessing the Addenda or LDS files. should contact ESRDPayment@ cms.hhs.gov.

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 413—PRINCIPLES OF **REASONABLE COST** REIMBURSEMENT; PAYMENT FOR **END-STAGE RENAL DISEASE** SERVICES; PROSPECTIVELY **DETERMINED PAYMENT RATES FOR** SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY **INJURY DIALYSIS**

■ 1. The authority citation for part 413 continues to read as follows:

Authority: Secs. 1102, 1812(d), 1814(b). 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww); and sec. 124 of Public Law 106-113, 113 Stat. 1501A-332; sec. 3201 of Public Law 112-96. 126 Stat. 156; sec. 632 of Public Law 112-240, 126 Stat. 2354; sec. 217 of Public Law 113-93, 129 Stat. 1040; and sec. 204 of Public Law 113-295, 128 Stat. 4010; and sec. 808 of Public Law 114-27, 129 Stat. 362.

■ 2. Section 413.177(a) is revised to read as follows:

§ 413.177 Quality incentive program payment.

- (a) With respect to renal dialysis services as defined under § 413.171, in the case of an ESRD facility that does not earn enough points under the program described at § 413.178 to meet or exceed the minimum total performance score (as defined at § 413.178(a)(8)) established by CMS for a payment year (as defined at § 413.178(a)(10)), payments otherwise made to the facility under § 413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:
- (1) For every 10 points that the total performance score (as defined at § 413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

- (2) [Reserved]

■ 3. Section 413.178 is added to read as

§ 413.178 ESRD quality incentive program.

- (a) Definitions. As used in this section:
- (1) Achievement threshold means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.
- (2) Baseline period means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.
- (3) Benchmark means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment vear.
- (4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (d)(1)(i) through (iii) of this section.
- (5) End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) means the program authorized under section 1881(h) of the Social Security Act.
- (6) ESRD facility means an ESRD facility as defined in § 413.171.
- (7) Improvement threshold means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.
- (8) Minimum total performance score (mTPS) means, with respect to a payment year, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.
- (9) Payment reduction means the reduction, as specified by CMS, to each payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.
- (10) Payment year means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.
- (11) Performance period means the time period during which data are

collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment

(12) Performance standards are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) Reporting measure means a measure that is scored for a payment year using the methodology described in paragraph (d)(1)(iv) of this section.

(14) Total performance score (TPS) means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment

(b) Applicability of the ESRD QIP. The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number

(CCN) effective date.

- (c) ESRD QIP measure selection. CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include, but are not limited to:
- (1) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management.
- (2) Measures on dialysis adequacy. (3) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access

(including for maximizing the placement of arterial venous fistula).

(4) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomesbased.

- (d) Performance scoring under the ESRD QIP. (1) CMS will award points to an ESRD facility based on its performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment
- (i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds

the achievement threshold but is less than the benchmark specified for that

(ii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iii) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

- (iv) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.
- (2) CMS calculates the TPS for an ESRD facility for a payment year as
- (i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (d)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.
- (ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the

payment year.

(e) Public availability of ESRD QIP performance information. (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (e)(1) of this section available to the public, CMS will provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS

issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(f) Limitation on review. There is no administrative or judicial review of the

following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

- (3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.
- (4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.
- 4. Section 413.232 is amended by—
- a. Revising paragraphs (b) introductory text and (b)(2)
- b. Revising paragraph (c)(2);
- c. Revising paragraph (e);
- d. Revising paragraph (g)(2); and
- e. Adding paragraph (g)(3).

The revisions and addition read as follows:

§ 413.232 Low-volume adjustment.

(b) Definition of low-volume facility. A low-volume facility is an ESRD facility that, as determined based on the

documentation submitted pursuant to paragraph (g) of this section:

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

(2) Five (5) road miles or less from the ESRD facility in question.

* * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment vear, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, for calendar year 2015, the attestation must be provided by December 31, 2014, and for calendar year 2016, the attestation must be provided by December 31, 2015.

(g) * * *

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 consecutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

- (3) In the case of an ESRD facility that has changed their cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:
- (i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or
- (ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.
- 5. Section 413.234 is amended—
- a. In paragraph (a) by removing the definition of "New injectable or intravenous product" and adding the definition of "New renal dialysis drug or biological" in alphabetical order; and
- b. By revising paragraphs (b) and (c).
 The revisions read as follows:

$\S 413.234$ Drug designation process.

(a) * * *

New renal dialysis drug or biological. An injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs or biologicals are excluded until January 1, 2025.

* * * * *

(b) *Drug designation process*. New renal dialysis drugs or biologicals are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological is added to an existing ESRD

PPS functional category.

(ii) The new renal dialysis drug or biological is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(2) If the new renal dialysis drug or biological is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new renal dialysis drug or biological is used to treat or manage;

(ii) The new renal dialysis drug or biological is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

- (c) Transitional drug add-on payment adjustment. A new renal dialysis drug or biological is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of Average Sales Price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the payment would be based on the drug manufacturer's invoice.
- (1) A new renal dialysis drug or biological that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment is paid for 2 years.
- (i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.
 - (ii) [Reserved]
- (2) A new renal dialysis drug or biological that is not considered

included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

* * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

- 7. Section 414.210 is amended by—
- \blacksquare a. Revising paragraphs (g)(4), (7) and (9); and
- b. Adding paragraph (g)(10).

 The revisions and addition read as follows:

§ 414.210 General payment rules.

(g) * * *

(4) Payment adjustments using data on items and services included in competitive bidding programs no longer in effect. In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI-U for the 12-month period ending

6 months prior to the date the updated

payment adjustments would go into effect.

* * * * * *

- (7) Payment adjustments for mail order items furnished in the Northern Mariana Islands. The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph would no longer apply.
- (9) Transition rules. The payment adjustments described above are phased in as follows:
- (i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.
- (ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.
- (iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.
- (iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.
- (10) Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP. During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last

day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

■ 8. Section 414.222 is amended by adding paragraph (f) to read as follows:

§ 414.222 Items requiring frequent and substantial servicing.

* * * * * *

(f) Multi-function ventilators—(1)
Definition. For the purpose of this
paragraph, a multi-function ventilator is
a ventilator as defined in paragraph
(a)(1) of this section that also performs
medically necessary functions for the
patient at the same time that would
otherwise be performed by one or more
different items classified under

§ 414.220, § 414.226, or § 414.229. (2) Payment rule. Effective for dates of service on or after January 1, 2019, the monthly rental fee schedule amount for a multi-function ventilator described in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3), increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) Monthly cost for additional functions. (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under § 414.226, the monthly cost is equal to the monthly payment amount established in § 414.226(e), (f),

and (g) of, adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under § 414.229, the monthly cost is equal to the purchase price established in § 414.229 (c) of, adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

- 9. Section 414.226 is amended—
- a. By revising the heading of paragraph (c);
- b. By revising paragraph (c)(6);
- c. By revising the heading of paragraph (d);
- d. In paragraph (d)(2) by removing the reference "paragraph (e)(2)" and adding in its place the reference "paragraph (g)(2)";
- e. By redesignating paragraphs (e), (f) and (g) as paragraphs (g), (h), and (i); and
- f. By adding new paragraphs (e) and (f).

The revisions and additions read as follows:

§ 414.226 Oxygen and oxygen equipment.

(c) Monthly fee schedule amount for items furnished from 2007 through 2018.* * *

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) Application of monthly fee schedule amounts for items furnished from 2007 through 2018. * * *

* * * * *

(e) Monthly fee schedule amount for items furnished for years after 2018. (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.(iv) Oxygen generating portable

equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen

contents for prescribed flow rates greater than four liters per minute.

- (vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.
- (2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).
- (3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).
- (4) The monthly payment rate for items described in paragraph (e)(1)(vii) of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).
- (5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.
- (f) Application of monthly fee schedule amounts for items furnished for years after 2018. (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.
- (2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.
- (3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary-
- (i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or
- (ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.
- (4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary-

- (i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or
- (ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or
- (iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this
- (5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—
- (i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or
- (ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or
- (iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

§414.230 [Amended]

- 10. Section 414.230 is amended in paragraph (h) by removing the reference "§ 414.226(f)" and adding in its place the reference "§ 414.226(h)".
- 11. Section 414.402 is amended by revising the definitions of "Bid" and "Composite bid", and adding the definition of "Lead item" in alphabetical order to read as follows:

§414.402 Definitions.

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Composite bid means the bid submitted by the supplier for the lead item in the product category. *

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

- 12. Section 414.412 is amended by-
- \blacksquare a. Revising paragraphs (b)(1) and (2);
- b. Revising paragraph (c);
- c. Revising the heading of paragraph (e); and
- d. Revising the heading of paragraph

The revisions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* *

(b) * * *

- (1) Composite bids, as defined in § 414.402, are submitted for lead items, as defined in § 414.402.
- (2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under subpart C of this part, without the application of § 414.210(g), or subpart D of this part, without the application of § 414.105.

(c) Furnishing of items. A bid must include all costs related to furnishing all items in the product category, including all services directly related to the furnishing of the items.

(e) Commonly-owned or controlled suppliers. * * *

(h) Requiring bid surety bonds for bidding entities. * * * *

■ 13. Section 414.414 is amended by revising paragraph (e) to read as follows:

§ 414.414 Conditions for awarding contracts.

(e) Evaluation of bids. CMS evaluates composite bids submitted for a lead item within a product category by-

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

- (2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;
- (3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;
- (4) Calculating the pivotal bid for the product category; and
- (5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.
- 14. Section 414.416 is amended by revising paragraph (b) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * * *

(b) Methodology for setting payment amount. (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum or highest bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to the amount that would otherwise be paid for the same item under subpart C

or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product

category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

§414.422 [Amended]

- 15. Section 414.422 is amended by redesignating paragraphs (d)(4)(iii) through (d)(4)(vi) as paragraphs (d)(4)(ii) through (d)(4)(v).
- 16. Section 414.423 is amended by revising paragraph (i)(8) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

(i) * * *

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

Dated: June 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 28, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–14986 Filed 7–11–18; 4:15 pm]

BILLING CODE P



FEDERAL REGISTER

Vol. 83 Thursday,

No. 139 July 19, 2018

Part III

Department of Transportation

Federal Transit Administration

49 CFR Part 673

Public Transportation Agency Safety Plan; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 673

[Docket No. FTA-2015-0021]

RIN 2132-AB23

Public Transportation Agency Safety Plan

AGENCY: Federal Transit Administration

(FTA), DOT.

ACTION: Final rule.

SUMMARY: The Federal Transit Administration (FTA) is publishing a final rule for Public Transportation Agency Safety Plans as authorized by the Moving Ahead for Progress in the 21st Century Act (MAP-21). This final rule requires States and certain operators of public transportation systems that receive Federal financial assistance under 49 U.S.C. Chapter 53 to develop Public Transportation Agency Safety Plans based on the Safety Management System approach. Operators of public transportation systems will be required to implement the safety plans. The development and implementation of safety plans will help ensure that public transportation systems are safe nationwide.

DATES: The effective date of this rule is July 19, 2019.

FTA's Office of Transit Safety and Oversight (TSO) will host a series of webinars to discuss the requirements of the Public Transportation Agency Safety Plan (PTASP) final rule. The first two webinars will be held at 2 p.m. on Wednesday, July 25, 2018 and Tuesday, July 31, 2018.

ADDRESSES: To register for webinars and for information about future webinars, please visit https://www.transit.dot.gov/about/events.

FTA is committed to providing equal access for all webinar participants. If you need alternative formats, options, or services, contact FTA-Knowledge@dot.gov at least three business days prior to the event. If you have any questions, please email FTA-Knowledge@dot.gov.

FOR FURTHER INFORMATION CONTACT: For general information, contact PTASP_QA@dot.gov. For program matters, contact Adrianne Malasky, Office of Transit Safety and Oversight, (202) 366–1783 or Adrianne.Malasky@dot.gov. For legal matters, contact Michael Culotta, Office of Chief Counsel, (212) 668–2170 or Michael.Culotta@dot.gov. Office hours are from 8:30 a.m. to 5:00 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of Regulatory Action
 - B. Legal Authority
 - C. Summary of Major Provisions
 - 1. Summary of the Final Rule
 - 2. Summary of Public Comments
 - 3. Summary of the Major Changes to the Rule
 - D. Costs and Benefits
- II. Background
- III. Notice of Proposed Rulemaking and Response to Relevant Comments
 - A. Scope and Applicability of Public Transportation Agency Safety Plans
 - 1. Section 5310, Section 5311, Small Section 5307, and Tribal Operators
 - 2. Commuter Rail and Passenger Ferry Service
 - 3. Contracted Service
- B. Definitions
- 1. Accident
- 2. Incident
- 3. Occurrence
- 4. Serious Injury
- 5. Accountable Executive
- 6. Chief Safety Officer
- 7. Operator of a Public Transportation System
- 8. Rail Transit Agency
- 9. Performance Target, Safety Performance Target, and Performance Criteria
- 10. Small Public Transportation Provider
- 11. Requests for New Definitions
- C. General Requirements
- 1. Role of the Accountable Executive
- 2. Approval of a Public Transportation Agency Safety Plan
- 3. Documentation of SMS Processes and Activities
- 4. Safety Performance Targets
- Future Requirements in FTA's Public Transportation Safety Program and National Public Transportation Safety Plan
- 6. Process and Timeline for Annual Review and Update
- 7. Emergency Preparedness and Response Plans
- 8. Multiple Modes of Transit Service
- D. State and Transit Agency Roles
- 1. Large Transit Agencies
- Small Public Transportation Providers, Section 5311 Providers, and Section 5310 Providers
- 2.1. States Must Draft and Certify Safety Plans on Behalf of Small Public Transportation Providers
- 2.1.1. Option for State-Wide or Agency-Specific Safety Plans
- 2.1.2. Drafting and Certifying Safety Plans for Small Section 5307 Providers
- 2.2. Other Comments
- 3. Small Transit Providers May Draft and Certify Their Own Safety Plans
- 4. Direct and Designated Recipients
 Drafting and Certifying Safety Plans on
 Behalf of Smaller Transit Providers
- E. Existing System Safety Program Plan Is Effective for One Year
- 1. General Comments
- 2. One-Year Compliance Timeframe
- F. Certification of Safety Plans
- G. SSOA Review and Approval of PTASPs for Rail Transit Systems

- H. Safety Performance Targets and Performance-Based Planning
- I. Safety Management Systems
- 1. Safety Management Policy: General Comments
- 1.1. Safety Management Policy Statement
- 1.2. Employee Reporting Program
- 1.3. Safety Accountabilities and Responsibilities
- 2. Safety Risk Management
- 2.1. Safety Risk Management: General Comments
- 2.2. Safety Hazard Identification and Analysis
- 3. Safety Assurance
- 3.1. Safety Assurance: Safety Performance Monitoring and Measurement
- 3.2. Safety Assurance: Management of Change
- 3.3. Safety Assurance: Continuous Improvement
- 4. Safety Promotion
- 5. Scalability of SMS
- 6. SMS and Safety Culture
- J. Safety Plan Documentation and Recordkeeping
- 1. Safety Plan Documentation
- 2. Safety Plan Records
- 3. Other Comments on Documentation and Recordkeeping
- 4. Database Systems
- 5. Staffing and Resources as a Result of Documentation and Recordkeeping
- K. Funding
- L. Staffing
- M. Enforcement and Oversight
- 1. Triennial Reviews and State Management Reviews
- 2. State Oversight
- 3. Other Comments
- N. NTD Reporting
- O. Security
- P. SSPP-PTASP Crosswalk
- Q. Safety Performance Measures
- R. Technical Assistance and Guidance
- S. Coordination With Other Entities
- T. Nexus Between the PTASP Rule and Other FTA Requirements
- U. Americans With Disabilities Act Issues
- V. Other Comments on the Rule W. Regulatory Impact Analyses
- 1. Costs
- 2. Benefits
- 3. Regulatory Flexibility Act
- X. Tribal Issues
- 1. Applicability of the Rule to Tribes
- 2. The State's Role in Tribal Safety Plans
- 3. Financial Impact on Tribes
- 4. Tribal Consultation
- IV. Section-by-Section Analysis V. Regulatory Analyses and Notices

I. Executive Summary

A. Purpose of Regulatory Action

The public transportation industry remains among the safest surface transportation modes in terms of total reported safety events, fatalities, and injuries. Nonetheless, given public

¹ See United States Department of Transportation, Bureau of Transportation Statistics, "Table 2–1: Transportation Fatalities by Mode 1960–2016," at https://www.bts.gov/archive/publications/national transportation statistics/table 02 01; and "Table

transportation service complexities, the condition of transit equipment and facilities, turnover in the transit workforce, and the quality of policies, procedures, and training, the public transportation industry remains vulnerable to catastrophic accidents.

This rule outlines requirements for Public Transportation Agency Safety Plans that would carry out explicit statutory mandates in the Moving Ahead for Progress in the 21st Century Act (Pub. L. 112-141; July 6, 2012) (MAP-21), which was reauthorized by the Fixing America's Surface Transportation Act (Pub. L. 114–94; December 4, 2015) (FAST Act) and codified at 49 U.S.C. 5329(d), to strengthen the safety of public transportation systems that receive Federal financial assistance under 49 U.S.C. Chapter 53. This rule requires the adoption of Safety Management Systems (SMS) principles and methods; the development, certification, implementation, and update of Public Transportation Agency Safety Plans; and the coordination of Public Transportation Agency Safety Plan elements with other FTA programs and rules, as specified in 49 U.S.C. 5303, 5304, and 5329.

B. Legal Authority

In Section 20021 of MAP–21, which is codified at 49 U.S.C. 5329, Congress directed FTA to establish a comprehensive Public Transportation Safety Program, one element of which is the requirement for Public Transportation Agency Safety Plans. Pursuant to 49 U.S.C. 5329(d), FTA must issue a final rule requiring operators of public transportation systems that receive financial assistance under Chapter 53 to develop and certify Public Transportation Agency Safety Plans.

C. Summary of Major Provisions

1. Summary of the Final Rule

This rule adds a new part 673, "Public Transportation Agency Safety Plans," to Title 49 of the Code of Federal Regulations. The rule implements the requirements of 49 U.S.C. 5329(d).

One year after the effective date of this rule, each State, local governmental authority, and any other operator of a public transportation system that receives Federal financial assistance under 49 U.S.C. Chapter 53, must certify that it has established a comprehensive Public Transportation Agency Safety Plan (PTASP). 49 U.S.C. 5329(d)(1). At this time, the rule does not apply to an operator of a public transportation system that only receives Federal financial assistance under 49 U.S.C. 5310 (Section 5310), 49 U.S.C. 5311 (Section 5311), or both 49 U.S.C. 5310 and 49 U.S.C. 5311. Large transit providers must develop their own plans, have the plans approved by their Boards of Directors (or equivalent authorities), and certify to FTA that those plans are in place and comply with this part. Small public transportation providers that receive Urbanized Area Formula Program under 49 U.S.C. 5307 may have their plans drafted or certified by the State in which they operate. A small public transportation provider may opt to draft and certify its own plan.

At a minimum, and consistent with 49 U.S.C. 5329(d), each Public Transportation Agency Safety Plan must:

- Include the documented processes and procedures for the transit agency's Safety Management System, which consists of four main elements: (1) Safety Management Policy, (2) Safety Risk Management, (3) Safety Assurance, and (4) Safety Promotion, as discussed in more detail below (49 CFR 673.11(a)(2));
- Include performance targets based on the safety performance criteria established under the National Public Transportation Safety Plan (49 CFR 673.11(a)(3));
- Address all applicable requirements and standards as set forth in FTA's Public Transportation Safety Program and National Public Transportation Safety Plan (49 CFR 673.11(a)(4)); and
- Establish a process and timeline for conducting an annual review and update of the Public Transportation Agency Safety Plan (49 CFR 673.11(a)(5)).

Each rail transit agency must include in its Public Transportation Agency Safety Plan an emergency preparedness and response plan, as historically required by FTA under the former regulatory provisions of the State Safety Oversight rule at 49 CFR part 659 (49 CFR 673.11(a)(6)).

A transit agency may develop one Public Transportation Agency Safety Plan for all modes of its service, or it may develop a Public Transportation Agency Safety Plan for each mode of service that is not subject to safety regulation by another Federal entity. 49 CFR 673.11(b). A transit agency must maintain records associated with its Public Transportation Agency Safety Plan. 49 CFR 673 subpart D. Any rail fixed guideway public transportation system that had a System Safety

Program Plan (SSPP) compliant with the former regulatory provisions of 49 CFR part 659 as of October 1, 2012, may keep that plan in effect until one year after the effective date of this rule. 49 CFR 673.11(e). A transit agency that operates passenger ferry service regulated by the United States Coast Guard (USCG) or rail fixed guideway public transportation service regulated by the Federal Railroad Administration (FRA) is not required to develop a Public Transportation Agency Safety Plan for those modes of service. 49 CFR 673.11(f).

States and transit agencies must make their safety performance targets available to States and Metropolitan Planning Organizations (MPO) to aid in the planning process, and to the maximum extent practicable, States and transit agencies must coordinate with States and MPOs in the selection of State and MPO safety performance targets. 49 CFR 673.15.

On an annual basis, transit agencies and States must certify compliance with this rule. 49 CFR 673.13.

2. Summary of Public Comments

On February 5, 2016, FTA issued a Notice of Proposed Rulemaking (NPRM) for Public Transportation Agency Safety Plans. 81 FR 6344 (https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02017.pdf). The public comment period closed on April 5, 2016. FTA received approximately 647 comments from approximately 77 entities, including States, transit agencies, trade associations, and individuals.

The majority of the comments addressed the administration of the rule. Over 100 comments focused on definitions, with the vast majority of those commenters requesting FTA to align terms and definitions with the terms and definitions that FTA recently finalized in other rules, such as the State Safety Oversight rule at 49 CFR part 674 and the Transit Asset Management rule at 49 CFR part 625. FTA received nearly 300 comments on issues relating to (1) the effective date and compliance date of the rule; (2) the drafting and certification of safety plans on behalf of recipients of FTA's Enhanced Mobility of Seniors and Individuals with Disabilities Program at 49 U.S.C. 5310 and other smaller recipients; (3) clarification of FTA's oversight process; (4) the need for FTA's technical assistance; (5) documentation and recordkeeping; and (6) the applicability of the rule.

FTA received over 80 comments on SMS. Many of the commenters expressed support for SMS, particularly given its flexibility and scalability.

^{1–40:} U.S. Passenger Miles (Millions) 1960–2015," at https://www.bts.gov/archive/publications/national_transportation_statistics/table_01_40.

Some commenters requested clarification of the flexibility and scalability of SMS, and to that end, they requested that FTA develop and issue a safety plan template. Other commenters requested clarification regarding specific provisions of SMS. In the NPRM, FTA sought comments on alternative regulatory frameworks to SMS, and in response to this request, FTA received no comments.

Detailed comment summaries and responses are below.

3. Summary of the Major Changes to the Rule

In response to the public comments, FTA made a number of changes to the rule. Below is a summary of those changes, which are discussed in more detail in the sections that follow.

Section 673.1 Applicability

In the NPRM, FTA proposed to apply the rule to every "State, local governmental authority, and any other operator of a public transportation system that receives Federal financial assistance under 49 U.S.C. Chapter 53." FTA specifically asked the public whether the rule should apply to recipients and subrecipients of funds under FTA's Enhanced Mobility of Seniors and Individuals with Disabilities Program at 49 U.S.C. 5310 (Section 5310). FTA also specifically asked the public for alternative regulatory frameworks that satisfy the statutory requirements of 49 U.S.C. 5329 and are tailored to fit the needs of smaller operators of public transportation.

FTA received numerous comments in response to these questions and the regulatory proposal. Several commenters suggested that FTA exempt Section 5310 recipients from the rule because they are smaller non-traditional transit providers. Several commenters suggested that FTA adopt a more streamlined and simplified approach that is more tailored for smaller operators. At least one commenter suggested that FTA exempt subrecipients of Section 5311 Rural Area Formula Program funds from the

In light of these public comments and the need for further evaluation, FTA is deferring regulatory action at this time on operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. This deferral will provide FTA time to further evaluate information and safety data related to these systems to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these systems. Thus,

this final rule does not address operators of public transportation systems that only receive Federal financial assistance under 49 U.S.C. 5310, 49 U.S.C. 5311, or both 49 U.S.C. 5310 and 49 U.S.C. 5311.

Section 673.5 Definitions

FTA updated the definitions of the terms "Accountable Executive" and "Transit Asset Management Plan," and FTA changed the term "Performance Criteria" to "Performance Measure," in an effort to align these terms and definitions with those in FTA's Transit Asset Management rule at 49 CFR part 625, which was published on July 26, 2016. FTA updated the definition of the term "Safety Risk Management," added the term "Rail Fixed Guideway Public Transportation System," and changed the term "Safety Risk" to "Risk" in an effort to align these terms and definitions with those in FTA's State Safety Oversight rule at 49 CFR part 674, which was published on March 16, 2016. FTA clarified in its definition of "Safety Management System Executive" that it means a "Chief" Safety Officer or an equivalent, FTA changed the term "Safety Risk Evaluation" to "Safety Risk Assessment" to add clarity to the final rule.

In the NPRM, FTA proposed to define "operator of a public transportation system" to exclude operators that "provide service that is closed to the general public and only available for a particular clientele." This language was intended to narrow the type of Section 5310 recipients that would be subject to the rule. In light of FTA's decision to defer action on the applicability of the rule to all Section 5310 recipients and subrecipients—including operators that "provide service that is closed to the general public and only available for a particular clientele"—FTA is removing this language from the definition of "operator of a public transportation system.'

In the NPRM, FTA proposed to define "Small Public Transportation Provider" to mean "a recipient or subrecipient of Urbanized Area Formula Program funds under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in revenue service and does not operate a rail fixed guideway public transportation system." In response to public comments and for consistency with the Transit Asset Management Rule (81 FR 48889), FTA changed the definition of the term "Small Public Transportation Provider" to mean 100 or fewer vehicles in "peak" revenue service, as opposed to revenue service generally.

Section 673.11(a)(6) General Requirements: Emergency Preparedness and Response Plans

Based on public comments, FTA will provide rail transit agencies with the option to either include an emergency preparedness and response plan as a section of their Public Transportation Agency Safety Plan, or they may incorporate an existing emergency preparedness and response plan into their Public Transportation Agency Safety Plan by reference.

Section 673.11(d) General Requirements; § 673.13 Certification of Compliance: The Drafting and Certification of Public Transportation Agency Safety Plans on Behalf of Section 5310 Recipients and Subrecipients

In the NPRM, FTA proposed to require States to draft and certify safety plans on behalf of certain recipients and subrecipients of funds under Section 5310 and the Section 5311 Formula Grants for Rural Areas Program. In light of the public comments from these recipients requesting exemptions from the rule and a more streamlined and tailored regulatory approach for smaller operators, and given FTA has decided to defer action on applicability of the rule to Section 5310 and Section 5311 recipients and subrecipients, FTA does not need to require States to draft and certify safety plans for those recipients and subrecipients at this time.

Section 673.23(a) Safety Management Policy

In the NPRM, FTA proposed to require transit agencies to develop a written Safety Management Policy, which would include safety performance targets. FTA received numerous comments noting that FTA also was proposing to require transit agencies to set safety performance targets in the General Requirements section of the rule, so the requirement in the Safety Management Policy section appeared redundant. FTA agrees, and to eliminate any redundancies, FTA deleted that requirement from the Safety Management Policy section of the rule.

Section 673.25 Safety Risk Management

In response to comments, FTA revised its Safety Risk Management requirements to add clarity to the safety hazard identification, safety risk assessment, and safety risk mitigation processes in the final rule.

Section 673.27 Safety Assurance

In the NPRM, FTA proposed to require all transit agencies to develop

and implement a comprehensive Safety Assurance process. FTA proposed to require all transit agencies to develop and implement processes for (1) safety performance monitoring and measurement, (2) management of change, and (3) continuous improvement.

FTA received comments seeking clarity on one of the requirements related to safety performance monitoring and measurement, specifically, the requirement for each transit agency to "[m]onitor its operations to identify hazards not identified through the Safety Risk Management process established in § 673.25 of this subpart." 49 CFR 673.27(b)(2) (as proposed in the NPRM). Some commenters suggested that this requirement appeared redundant and duplicative of each of the requirements under Safety Risk Management. FTA agrees with these commenters, and to add clarity, reduce redundancy, and lower burdens, FTA eliminated this requirement from the final rule.

More significantly, FTA received numerous comments requesting a reduction in the regulatory requirements for small public transportation providers. Given the limited administrative and financial resources available to small public transportation providers, FTA believes that a reduction in their regulatory burdens is appropriate. To that end, and to address the concerns expressed by commenters, FTA eliminated significant Safety Assurance requirements for all small public transportation providers. In the final rule, small public transportation providers only need to develop processes for safety performance monitoring and measurement. Small public transportation providers are not required to develop and implement processes for management of change and continuous improvement. FTA believes that these changes in the final rule will reduce their burdens significantly. Rail fixed guideway public transportation systems and recipients and subrecipients of Federal financial assistance under 49 U.S.C. Chapter 53 that have more than one hundred vehicles in peak revenue service must develop and implement Safety Assurance processes that include all of the regulatory requirements under 49 CFR 673.27, specifically, processes for safety performance monitoring and measurement, management of change, and continuous improvement.

Section 673.29(a) Safety Promotion

In the NPRM, FTA proposed to require transit agencies to establish comprehensive safety training programs for staff and contractors directly responsible for "the management of" safety. FTA received several comments expressing confusion over this requirement and the requirements of FTA's proposed Safety Certification Training Program Rule, which applies to staff and contractors who responsible for safety "oversight" on rail transit systems. In an effort to respond to the commenters and to eliminate confusion, FTA struck the language "the management of" from the rule, so it now requires safety training for staff and contractors who are "directly responsible for safety."

Section 673.31 Safety Plan Documentation

In the NPRM, FTA proposed to require transit agencies to maintain their safety plan documents for a minimum of three years. To add clarity in the final rule, FTA is requiring transit agencies to maintain safety plan documents for three years "after they are created."

Also, in the NPRM, FTA proposed to require a number of additional records related to a Public Transportation Agency Safety Plan. Specifically, FTA proposed to require transit agencies to maintain records related to (1) safety risk mitigations, (2) results of safety performance assessments, and (3) employee safety training. FTA received numerous comments requesting reduced recordkeeping burdens. FTA also received numerous comments, in general, from smaller transit operators requesting reduced regulatory burdens.

Upon review of these comments, FTA has eliminated the recordkeeping requirements in proposed 49 CFR 673.33 in their entirety. FTA believes that the records developed and maintained in accordance with 49 CFR 673.31 are sufficient to ensure that transit agencies are complying with the requirements of the statute and this final rule. FTA believes that this change in the final rule significantly will reduce the administrative, financial, and regulatory burdens on all transit operators.

D. Costs and Benefits

As discussed in greater detail below, FTA was able to estimate some but not all of the rule's costs. FTA was able to estimate the costs for transit agencies to develop and implement Public Transportation Agency Safety Plans,

which are approximately \$41 million in the first year, and \$30 million in each subsequent year, with annualized costs of \$31 million discounted at 7 percent. These costs result from developing and certifying safety plans, documenting SMS processes and procedures, implementing SMS, and maintaining records. FTA was not able to estimate the costs of actions that transit agencies would be required to take to mitigate risk as a result of implementing this rule, such as vehicle modifications, additional training, technology investments, or changes to operating procedures and practices. It is not possible for FTA to anticipate the strategies and actions agencies may adopt to address safety risks, or the time period over which these actions would

FTA was unable to quantify the rule's benefits. To estimate safety benefits, one would need information regarding the causes of safety events and the factors that may cause future events. This information is generally unavailable in the public transportation sector, given the infrequency and diversity of the type of safety events that occur. In addition, one would need information about the safety problems that agencies are likely to find through implementation of their safety plans and the actions agencies are likely to take to address those problems. Instead of quantifying benefits, FTA estimated the potential safety benefits. The potential safety benefits are an estimate of the cost of all bus and rail safety events over a future 20-year period. The estimate is an extrapolation of the total cost of bus and rail events that occurred from 2010 to 2016.

Table 1 below shows the summary of the Costs and the Potential Benefits. The benefits of the rule primarily will result from mitigating actions, which largely are not accounted for in this analysis. FTA has not estimated the benefits of implementing the rule without mitigating actions, but expects they are unlikely to be large. Estimated costs for agencies' safety plans include certain activities that could yield safety improvements, such as improved communication, identification of hazards, and greater employee awareness, as well as increased accountability at the higher echelons of the organization. It is plausible that these activities alone could produce accident reductions that surpass the cost of developing the plan, though even greater reductions could be achieved in concert with other mitigating actions.

TABLE 1—SUMMARY OF THE COSTS AND THE POTENTIAL BENEFITS IF ADDITIONAL UNQUANTIFIED MITIGATION INVESTMENTS OCCUR

[2016 Dollars]

| | Current dollar value | 7% Dis- counted value | 3% Dis- counted value |
|------------------------------------|---|--------------------------|--------------------------|
| Qualitative Benefits | Reduced bus and rail safety incidents with mitigation actions. Reduced delays in operations. | | |
| Estimated Costs (20-Year Estimate) | \$602,485,710 | \$323,732,747 | \$450,749,898 |
| Unquantified Costs | • Investments associated with mitigating safety risks (such as additional training, vehicle modification, operational changes, maintenance, and information dissemination). | | |
| Estimated Cost (Annualized) | | 30,558,081 | 30,297,473 |

II. Background

On July 6, 2012, the President signed into law MAP–21 (Pub. L. 112–141). MAP–21 authorized a number of fundamental changes to the Federal transit programs at 49 U.S.C. Chapter 53. This rule addresses the Public Transportation Agency Safety Plan within the Public Transportation Safety Program authorized under 49 U.S.C. 5329. This authority was reauthorized when the President signed into law the FAST Act on December 4, 2015.

The Public Transportation Safety Program consists of several key elements: The National Public Transportation Safety Plan, authorized by 49 U.S.C. 5329(b); the Public Transportation Safety Certification Training Program, authorized by 49 U.S.C. 5329(c); the Public Transportation Agency Safety Plans, authorized by 49 U.S.C. 5329(d); and the State Safety Oversight Program, authorized by 49 U.S.C. 5329(e). FTA has issued rules and guidance, and it will continue to issue rules and guidance, to carry out all of these plans and programs under the rulemaking authority of 49 U.S.C. 5329 and 5334(a)(11).

On October 3, 2013, FTA issued an Advance Notice of Proposed Rulemaking (ANPRM) for Public Transportation Agency Safety Plans, the National Public Transportation Safety Plan, the Safety Certification Training Program, and a new Transit Asset Management System. 78 FR 61251 (http://www.gpo.gov/fdsys/pkg/FR-2013-10-03/pdf/2013-23921.pdf). Through the ANPRM, FTA sought comments on 123 questions related to the implementation of the public transportation safety program and transit asset management; 42 of the 123 questions specifically were related to Public Transportation Agency Safety

Plans. The public comment period for the ANPRM closed on January 2, 2014. In response to the ANPRM, FTA received comments from 167 entities, including States, transit agencies, trade associations, and individuals.

Following a comprehensive review of the comments, FTA issued several NPRMs for safety and transit asset management. In particular, FTA issued the NPRM for Public Transportation Agency Safety Plans on February 5, 2016. In this NPRM, FTA addressed comments related to the 42 questions in the ANPRM on Public Transportation Agency Safety Plans, specifically, question numbers 8-10, 17-31, 33-44, 47, 107-110, 112, and 116-121. Through the NPRM, FTA proposed to create a new part 673 in Title 49 of the Code of Federal Regulations, which would require each operator of a public transportation system to develop and implement a Public Transportation Agency Safety Plan. FTA proposed specific requirements for these safety plans in accordance with 49 U.S.C. 5329(d), including the following minimum requirements:

• An approval by the transit agency's board of directors, or an equivalent entity, and a signature from the transit agency's Accountable Executive;

- Documented processes and procedures for an SMS, which would include a Safety Management Policy, a process for Safety Risk Management, a process for Safety Assurance, and Safety Promotion;
- Performance targets based on the safety performance measures set out in the National Public Transportation Safety Plan;
- Compliance with FTA's Public Transportation Agency Safety Plan and FTA's Public Transportation Safety Program; and
- A process and timeline for conducting an annual review and

update of the plan. In addition, rail transit agencies would be required to include an emergency preparedness and response plan in their Public Transportation Agency Safety Plans.

In light of the public interest in this rulemaking, and in an effort to provide guidance on the proposal and to solicit well-informed comments, FTA conducted numerous public outreach sessions and a webinar series related to the NPRM. Specifically, on February 12, 2016, FTA conducted public outreach for tribes and hosted a Tribal Technical Assistance Workshop wherein FTA presented its proposed rule and responded to technical questions from tribes. FTA subsequently delivered the same presentation during a webinar series open to all members of the public on February 24, March 1, March 2, and March 3. On March 7, FTA delivered the same presentation at an outreach session hosted by the National Rural Transit Assistance Program, which also was open to all members of the public. During each of these public outreach sessions and the public webinar series, FTA received and responded to numerous technical questions regarding the NPRM. FTA recorded the presentations, including the question and answer sessions, and made available the following documents on the public docket for this rulemaking (Docket FTA-2015-0021): (1) FTA's PowerPoint Presentation from the public outreach sessions and public webinar series (https:// www.regulations.gov/document?D=FTA-2015-0021-0012); (2) a written transcript of FTA's public webinar of March 1, 2016 (https://www.regulations.gov/ document?D=FTA-2015-0021-0010); (3) a consolidated list of every Question and FTA Answer from the public outreach sessions and public webinar series (https://www.regulations.gov/

document?D=FTA-2015-0021-0041); and (4) the results of polling questions from FTA's public outreach sessions (https://www.regulations.gov/document?D=FTA-2015-0021-0011). FTA also uploaded onto YouTube an audiovisual recording of its webinar from March 1, 2016. The video is available at the following link: https://www.youtube.com/watch?v=FBj5HRat wGA&feature=youtu.be.

III. Notice of Proposed Rulemaking and Response to Relevant Comments

As stated above, FTA issued an NPRM for Public Transportation Agency Safety Plans on February 5, 2016. 81 FR 6344 (https://www.gpo.gov/fdsys/pkg/FR-2016-02-05/pdf/2016-02017.pdf). The public comment period for the NPRM subsequently closed on April 5, 2016. FTA received approximately 647 comments from approximately 77 entities, including States, transit agencies, trade associations, and individuals. FTA reviewed all of the comments and took them into consideration when developing today's final rule. Some comments were outside the scope of this rulemaking and FTA did not respond to comments that were

outside the scope.

FTA received a number of comments related to the definitions of terms that are defined in other safety rulemakings. For example, FTA received comments on the terms, "Accident," "Incident," and "Occurrence," which FTA defined in the NPRM to provide clarity regarding the types of safety "Events" that a transit agency should investigate, and these terms are defined in the State Safety Oversight (SSO) rulemaking. Given that the Public Transportation Agency Safety Plan rule has a more inclusive universe of stakeholders than the SSO rule, FTA is including responses to the majority of the comments that it received related to these and other definitions included in other safety rules, but in this final rule, FTA does not respond to comments related to reporting thresholds and other requirements under the final SSO rule. On March 16, 2016, FTA issued a final rule for State Safety Oversight (see https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05489.pdf for a discussion of comments received on these terms), and FTA has adopted definitions found in that rulemaking in this rulemaking, where appropriate. Similarly, FTA received several comments related to the definition of the term "State of Good Repair," which FTA was required to define in a rulemaking for transit asset management pursuant to 49 U.S.C. 5326. On July 26, 2016, FTA issued a final rule for Transit

Asset Management wherein FTA defines the term "State of Good Repair," and FTA has adopted that definition in this rulemaking. Please review the preamble of the Transit Asset Management final rule for FTA's responses to the comments that it received related to the proposed definition of "State of Good Repair" (see https://www.gpo.gov/fdsys/ pkg/FR-2016-07-26/pdf/2016-16883.pdf). Relatedly, a number of commenters noted inconsistencies with the definitions throughout FTA's several safety rulemakings. In response, FTA has aligned the definitions in today's rule with other safety rulemakings and the Transit Asset Management final rule to ensure consistency.

Below, the NPRM comments and responses are subdivided by their corresponding sections of the proposed rule and subject matter.

- A. Scope and Applicability of Public Transportation Agency Safety Plans
- 1. Section 5310, Section 5311, Small Section 5307, and Tribal Operators

Comments: Several commenters supported FTA's proposal to require States to draft and certify safety plans on behalf of recipients and subrecipients of FTA financial assistance through the Enhanced Mobility of Seniors and Individuals with Disabilities Program at Section 5310. Several commenters also supported FTA's proposal only to apply this rule to Section 5310 recipients and subrecipients that provide service open to the public, and not to apply this rule to Section 5310 recipients and subrecipients that provide service closed to the public and only available for a particular clientele.

Several commenters recommended that FTA exempt all Section 5310 recipients and subrecipients from this rule. These commenters asserted that many Section 5310 operators are not traditional transit agencies—they are human service organizations with a small transportation service, and they do not have sufficient staff, money, or resources to implement all aspects of a safety plan. One commenter stated that recipients and subrecipients of FTA financial assistance under Section 5310 and Section 5311 should not be considered operators of public transportation, and thus, they should not be subject to this rule. Several commenters also requested that tribal transit operators be excluded from the requirements of this rule.

A few commenters asserted that the proposed delineation between "general public" and "closed door" is ambiguous. These commenters

expressed concern that many smaller Section 5310 recipients may decide to discontinue transit service, thus reducing mobility for seniors and individuals with disabilities.

One commenter stated that any new regulations should be tailored for small operators, and that FTA should avoid adding additional requirements and regulatory burdens. This commenter requested that FTA consider an exemption for transit agencies that operate fewer than 30 vehicles in peak revenue service. Another commenter suggested requiring a limited set of streamlined and simplified requirements, without identifying what those requirements might be.

Response: FTA appreciates the comments that it received regarding the proposed applicability of this rule. Pursuant to the statutory requirements of 49 U.S.C. 5329(d), "each recipient or State" is required to draft and certify a safety plan. The statute defines "recipient" to mean "a State or local governmental authority, or any other operator of a public transportation system, that receives financial assistance under [49 U.S.C. Chapter 53]."

Notwithstanding this definition, and in light of the public comments and need for further evaluation, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. Further evaluation of information and safety data related to these operators is needed to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators. Consequently, the rule does not apply to an operator of a public transportation system that only receives Federal financial assistance under 49 U.S.C. 5310, 49 U.S.C. 5311, or both 49 U.S.C. 5310 and 49 U.S.C. 5311.

FTA disagrees with the suggestion to create a threshold of 30 vehicles in peak revenue service, and it is adopting the definition of "operator of a public transportation system" as "a provider of public transportation as defined under 49 U.S.C. 5302(14)."

FTA agrees with the commenters who suggested that the final rule should be tailored for small operators and that the final rule should have simplified requirements. To that end, and as discussed in more detail below, FTA eliminated several significant requirements related to Safety Assurance for all small public transportation providers. Additionally, FTA eliminated requirements for Safety Assurance and a series of recordkeeping

requirements for all transit operators, regardless of size, in an effort to reduce their administrative, financial, and regulatory burdens.

2. Commuter Rail and Passenger Ferry Service

Comments: Several commenters supported FTA's proposal to exclude from this rule rail fixed guideway public transportation (commuter rail) service regulated by FRA. Several commenters requested FTA to clarify that the rule applies to rail transit systems not subject to regulation by FRA. Three commenters requested FTA to clarify what it means to exclude rail transit agencies subject to regulation by another Federal agency. One commenter urged FTA to ensure that the rule does not duplicate the efforts of State Safety Oversight Agencies (SSOAs) and overly burden transit agencies.

One commenter suggested that FTA replace the term "commuter rail system" with the term "passenger rail system." This commenter stated that the term "commuter" is not defined in the rule, leaving no context for determining what types of rail systems would be excluded. The commenter also asserted that rail transit agencies might provide passenger rail service that is subject to FRA regulations, but that service may not be considered "commuter" service, thus resulting in a too-narrow description of "commuter" and a contradiction to FTA's intent to prevent "duplicative, inconsistent, or conflicting regulations."

Several commenters supported FTA's proposal to exclude from this rule passenger ferry service regulated by USCG. Two commenters expressed support for the exclusion of USCGinspected ferry vessels from the proposed rule. However, these commenters suggested that FTA should revise the term "passenger ferries" to clarify that the exclusion refers to passenger-only ferry vessels and ferry vessels that carry both passengers and vehicles (the commenters suggested the phrase "ferry as defined by title 46 United States Code 2101(10b)"). Additionally, this commenter urged FTA to clarify that the exclusion of USCG-inspected vessels applies to subparts C and D of the proposed rule, in addition to subpart B.

Response: FTA appreciates the support for its proposal to exclude passenger rail service regulated by FRA and passenger ferry service regulated by USCG from the requirements of this rule. As discussed throughout this document, this rule applies to each operator of a public transportation system, including rail fixed guideway

public transportation passenger rail service that is not regulated by another Federal agency. To further clarify, to the extent that an operator of a public transportation system provides passenger rail service that is regulated by FRA and rail fixed guideway public transportation service that is not regulated by FRA, this rule only would apply to that portion of the rail fixed guideway public transportation service that is not regulated by FRA.

FTA appreciates the concerns regarding the use of the term "commuter rail system," which is not defined in this rule, and the suggestion to replace the term "commuter rail system" with the term "passenger rail system." Instead, in an effort to use terms consistently throughout all of FTA's rules and regulations, FTA is replacing the term "commuter rail system" with the term "rail fixed guideway public transportation" and is adopting the definition of this term as used in FTA's new State Safety Oversight (SSO) rule at 49 CFR part 674.

With respect to passenger ferry service, FTA clarifies that this rule would not apply to any passenger ferry service that is regulated by USCG, including passenger ferry service and ferry service that involves the transportation of both passengers and vehicles. The exclusion of ferry service regulated by USCG applies to the rule in its entirety.

3. Contracted Service

Comments: Several commenters requested FTA to clarify how the rule would apply to transit agencies that contract for transit service. A commenter stated that the proposed elements of PTASPs are being implemented in the majority of transit systems operated by contractors, but contractors generally do not have direct relationships with transit agencies' top leadership. A commenter requested that FTA clarify how contracted agencies should divide roles and responsibilities and implement SMS without having to revisit existing contractual agreements. This commenter also encouraged FTA to provide additional technical assistance to assist agencies operating in contract environments in the development and implementation of PTASPs. Another transit agency urged FTA to clarify the extent to which the implementation and administration of SMS principles could be delegated to contractors. One commenter stated that if inter-city bus service is contracted, then the contractor, not the transit agency, should have primary responsibility for safety and compliance with the rule.

Two commenters asked FTA to clarify the rule's application to paratransit service. One of these commenters requested clarification as to how the rule would apply to an instance where a contractor provides paratransit service for a Section 5311 recipient and a separate Section 5310 recipient.

Response: As noted above, the statutory provisions of 49 U.S.C. 5329(d) require each "State or local governmental authority, or any other operator of a public transportation system, that receives financial assistance under [49 U.S.C. Chapter 53]" to draft and certify a safety plan. Consequently, this rule applies to FTA's recipients and subrecipients, unless the transit operator only receives Section 5310 and/or Section 5311 funds. To the extent that a recipient or subrecipient contracts for transit service, FTA will defer to the recipient or subrecipient to ensure that each of the requirements of this rule are being satisfied through the terms and conditions of its contract, including the identification of safety roles and responsibilities. Ultimately, under the statute, each FTA recipient or subrecipient has the responsibility to ensure compliance with this rule and to certify compliance annually—not a contractor.

Similarly, paratransit service—whether general public or ADA complementary, and including contracted paratransit service—is subject to this rule, unless the transit operator only receives Section 5310 and/or Section 5311 funds. To the extent that a contractor provides paratransit service for multiple FTA recipients, each FTA recipient ultimately has responsibility for ensuring that its transit operation complies with this rule.

B. Definitions

1. Accident

Comment: Several commenters expressed concerns with the proposed definition of "Accident." Many of these commenters expressed concern with the phrase "a report of a serious injury to a person" within the definition of Accident. One commenter stated that "serious injury" relies on information that a transit agency is unlikely to possess or be able to validate. Another commenter expressed that this phrase would significantly increase transit agencies' notification and follow-up burdens. One commenter stated that the term "Accident" is a bias-laden term which suggests that an undesirable event could not be foreseen, prevented, or avoided. This commenter also asserted that the continued use of this

term diminishes advances made by safety and risk management professionals to adopt and promote biasfree language describing and categorizing incidents. Another commenter suggested that the proposed definition offers several categorizations for accidents without regard to cause, circumstance, or affected environment.

Several commenters suggested alternatives for the proposed definition of "Accident." A commenter recommended using the threshold for accident notification in the former SSO rule at 49 CFR 659.33: "[M]edical attention away from the scene for two or more individuals." Another commenter proposed that the definition for 'Accident'' should include a threshold of at least \$100,000, otherwise every minor collision would be reportable in accordance with 49 CFR part 674, creating a burden on rail transit agencies' resources. This commenter suggested that accidents which result in property damage of \$100,000 or less be classified as "incidents," and be reportable to the SSOA and FTA, with a corresponding report to the National Transit Database (NTD) within thirty days. Another commenter remarked that the proposed definition of "Accident" should be more applicable to rail and bus/paratransit operations by using separate definitions for train and bus/ paratransit accidents. For bus/ paratransit, the commenter recommended that FTA should use the current Federal Motor Carrier Safety Administration (FMCSA) definition for "Accident" found in 49 CFR part 390. The commenter suggested that FTA could use an amended version of their proposed definition for "Accident" for rail operations that replaces "a report of serious injury to a person," with "injuries requiring immediate medical attention away from the scene for two or more individuals.'

Response: FTA included the definition of "Accident" in the proposed rule because the term appears in the definition of "Event" which is mentioned in the Safety Assurance section of the NPRM (a transit agency must develop a process to "[i]nvestigate safety events to identify causal factors"). FTA defined "Event" as an "Accident, Incident, or Occurrence," and to provide guidance to the industry on these terms, FTA defined them in its safety rules. Notably, FTA finalized a definition for "Accident" in its new SSO rule at 49 CFR part 674, and FTA is adopting that definition in today's rule to ensure consistency throughout FTA's regulatory framework for safety.

FTA did not propose any reporting or notification requirements in this rule.

FTA established reporting and notification requirements in the new SSO rule at 49 CFR part 674 and FTA's NTD Reporting Manual. Today's rule requires transit agencies to develop safety plans, and this rule outlines the requirements for those plans. Accordingly, FTA will not amend those notification and reporting requirements through today's rule.

FTA disagrees with the commenter who suggested that the phrase "serious injury" will increase transit agencies notification and follow-up burdens; this language should simplify, streamline, and make consistent any follow-up process. FTA also disagrees with the commenter who stated that the term "Accident" is a bias-laden term. Its use is intended to define the universe of safety Events that must be investigated. FTA disagrees with the suggestion that the proposed definition offers several categorizations for Accidents without regard to cause, circumstance, or affected environment. FTA has offered clarification on this term in Appendix A to the new SSO rule at 49 CFR part 674 (https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05489.pdf).

FTA acknowledges that a transit agency may have difficulty ascertaining a precise type of injury due to medical privacy laws. FTA does not expect transit agencies to violate any medical privacy laws to determine whether an injury is serious. FTA does not expect transit agencies to seek medical records of individuals involved in Accidents that may have resulted in serious injuries.

FTA disagrees with the commenter who recommended using the threshold for accident notification in 49 CFR 659.33, "medical attention away from the scene for two or more individuals," as FTA believes that a serious injury to a single person is of sufficient concern to warrant designation as an "Accident." Additionally, ambulance transportation away from the scene may not necessarily be an accurate indicator of the actual gravity of the Event, given the possibility of ambulance operators transporting individuals with minor injuries.

FTA disagrees with the commenter who suggested that the definition of "Accident" include a threshold of at least \$100,000, and that Events which result in property damage of \$100,000 or less be classified as "Incidents." FTA did not utilize the original \$25,000 threshold for "Accident" in the SSO rule because most collisions involving rail transit vehicles exceeds \$25,000 in property or equipment damage and FTA believes that any threshold for property damage is arbitrary when determining

whether an Event qualifies as an Accident. Removal of the \$25,000 threshold also eliminates any need to separate rail transit property from non-rail transit property when making an assessment of damages.

Finally, FTA disagrees with the commenter who suggested that the proposed definition of "Accident" be made more applicable to rail and bus/paratransit by using separate definitions for train and bus/paratransit accidents. FTA intends to be consistent with its definitions, especially since this final rule applies to all operators of public transportation systems.

2. Incident

Comments: One commenter stated that the proposed definition of "Incident" seems broad and undefined, asserting that under the proposed definition, any reported injury could be classified as an Incident. Another commenter asked how to distinguish between medical transport for serious and non-serious injuries. A commenter asked FTA to clarify what is considered "damage to facilities, equipment, rolling stock, or infrastructure" and how "damage" would be assessed to determine qualification for an Incident. Additionally, the commenter asked how a transit agency would differentiate damage and a simple mechanical issue, and whether every defect found on an inspection would now be considered ''damage.'' This commenter also remarked that the terms "personal injury" and "injury," which are used in the definition for "Incident," are not defined. A commenter suggested that the definition of "Accident" would be the better place to include one or more injuries requiring medical transport away from the scene.

One commenter asked whether a transit agency must track Incidents. Another commenter stated that the Appendix to 49 CFR part 674 requires rail transit agencies to report Incidents to FTA using NTD within thirty days; the commenter asked whether transit agencies providing bus transportation also must report bus-related incidents to FTA using NTD.

Response: FTA included the definition of "Incident" in the proposed rule because the term appears in the definition of "Event" which is mentioned in the Safety Assurance section of the NPRM (a transit agency must develop a process to "[i]investigate safety events to identify causal factors"). FTA defined "Event" as an "Accident, Incident, or Occurrence," and to provide guidance to the industry on these terms, FTA defined them in its safety rules. Notably, FTA finalized a

definition for "Incident" in its new SSO rule at 49 CFR part 674, and FTA is adopting that definition in today's rule to ensure consistency throughout FTA's regulatory framework for safety.

FTA disagrees with the commenter who stated that the definition of "Incident" is broad and undefined and that any reported injury could be classified as an Incident. As discussed in more detail in response to the comments on the definition for "Serious Injury," FTA believes that there is a clear delineation between "serious injury" and "non-serious injury."

FTA provided guidance in Appendix A to 49 CFR part 674 on how to define "damage to facilities, equipment, rolling stock, or infrastructure" and how "damage" would be assessed to determine qualification for an Incident. In Appendix A, "damage" that meets the Incident threshold is any noncollision-related damage to equipment, rolling stock, or infrastructure that disrupts the operations of a transit agency. Ultimately, each transit agency must assess the safety risk associated with any damage to its equipment facilities, equipment, rolling stock, or infrastructure, and whether it meets the definition of Accident, Incident, or Occurrence.

FTA does not believe that it is necessary to define "injury" or "personal injury" in this rule, and it defines "Serious Injury" for purposes of establishing a threshold by which an Event would be considered an Accident instead of an Incident. In today's rule, FTA has revised the definitions of "Accident" and "Incident" to make them consistent with FTA's SSO rule at 49 CFR part 674. Under the updated definitions, one or more "serious injuries" is the threshold for Accident and one or more non-serious injuries requiring medical transport away from the scene is considered an Incident.

Under FTA's new SSO rule at 49 CFR part 674, a rail transit agency must track and report an "Incident" through NTD, as has been the historical practice. Furthermore, a transit agency also must report Incident information for other modes to FTA through NTD. Please refer to the NTD Reporting Manual for further information on what information is collected on safety Events as a well as Accidents and Incidents, for both rail transit and bus agencies.

3. Occurrence

Comments: One commenter asked how damage would be differentiated from mechanical issues or normal wearand-tear. This commenter asked FTA to clarify the relationship between "Occurrence" and "Injury" given that neither "personal injury" nor "injury" are defined in the rule. Another commenter asked FTA to define "disrupt transit operations." Finally, one commenter recommended omitting the proposed definition because it is too broad and does not serve a clear purpose.

Response: FTA included the definition of "Occurrence" in the proposed rule because the term appears in the definition of "Event" which is mentioned in the Safety Assurance section of the NPRM (a transit agency must develop a process to "[i]investigate safety events to identify causal factors"). FTA defined "Event" as an "Accident, Incident, or Occurrence," and to provide guidance to the industry on these terms, FTA defined them in its safety rules. Notably, FTA finalized a definition for "Occurrence" in its new SSO rule at 49 CFR part 674, and FTA is adopting that definition in today's rule to ensure consistency throughout FTA's regulatory framework for safety.

FTA believes that there is a clear distinction between damage and mechanical issues or normal wear and tear. Damage is physical harm done to something or someone. Mechanical issues and normal wear and tear are not the result of something or someone inflicting harm on equipment, facilities, equipment, rolling stock, or infrastructure.

A disruption to transit operations could be any interference with normal transit service at an agency. An Occurrence is a safety Event that only involves a disruption of transit service. A safety Event that results in a serious or non-serious injury would not be an Occurrence.

FTA disagrees with the commenter who suggested that FTA should omit the proposed definition of "Occurrence" because it does not serve a clear purpose. The definition helps identify the universe of activity that a transit agency should investigate because it could present a safety risk.

4. Serious Injury

Comments: Several commenters stated that transit agencies would not be able to obtain enough information about injuries to classify them as "serious," given Federal Health Insurance Portability and Accountability Act (HIPAA) privacy regulations. These commenters suggested that HIPAA privacy regulations prevent transit agencies from obtaining personal medical information from individuals involved in accidents. One commenter

remarked that, in their experience, hospital staff refused to provide personal medical information to a transit police officer.

One commenter recommended that FTA should explain how transit agencies and SSOAs can comply with this definition, and this commenter suggested that FTA create the legal authority for States to do so, or develop an alternative approach. A commenter remarked that if FTA has authority to obtain this type of information, then FTA should do so on its own accord. The commenter asked if it would meet one of the exemptions from the Government in the Sunshine Act if FTA collects information. One commenter asked how FTA would address and reconcile the proposed definition with other applicable Federal policies and regulations.

One commenter asked whether FTA would expect transit agencies, States, and SSOAs to obtain contact information for every individual involved in an accident, and then monitor local hospitals or contact these individuals in the seven-day period to determine if anyone involved in the accident had to be hospitalized for more than 48 hours as a result of this accident. Finally, one commenter asked whether a doctor would be required to respond to every transit event that has the possibility of being classified as an accident to triage the situation and determine whether the event meets the definition of an accident.

Several commenters expressed concern about the definition of "Serious Injury" and its associated burden on transit agency staff. A commenter concluded that the proposed definition would require transit agencies, States, and SSOAs to step outside their training to practice some form of medicine—for which they are not licensed—to comply with the proposed rule, unless transit agencies, States, and SSOAs are expected to hire trained medical personnel as a part of their programs. The commenter stated that transit agency staff may not be aware of the nature or extent of an individual's injury, and these staff may only know that an individual was transported away from the scene for medical attention with very limited ability (and no authority) to confirm the individual's injury status. A commenter stated that, in order to meet a similar FRA requirement, the commenter expends considerable resources following up on individual claims, and is sometimes unable to properly classify events for months or years after the event date. The commenter concluded that the resources needed to gather this

² See Merriam-Webster's Collegiate Dictionary (11th edition).

proposed information would be burdensome, as the volume of passengers is much greater for FTA.

A commenter asserted that transit agency staff could report certain findings on their initial incident reports, but this effort would be burdensome, and the transit agency staff would have to rely on eyewitness reports rather than medical professionals' opinions, rendering the effort unreliable. The commenter asked whether an initial patient/scene assessment would suffice, or whether a definitive medical diagnosis would be required.

Several commenters suggested alternatives to the proposed definition of "Serious Injury." Two commenters recommended that FTA use the definition in the former SSO rule at 49 CFR 659.33, which states that an accident involves injuries if there is a need for "immediate medical attention away from the scene for two or more individuals." According to these commenters, verifying transport away from the scene would have several benefits, such as: Not requiring transit agencies, States, and SSOAs to practice medicine to classify events; avoiding HIPAA complications; allowing events classified as accidents and incidents to be reported and investigated in a timely manner; being a more reasonable threshold for injury definitions; requiring only easily attainable information; and its alignment with NTD reporting requirements.

One commenter questioned how FTA determined the classification for "serious" and questioned how serious an injury could be if no medical treatment was sought for seven days. The commenter stated that FTA needs to define "serious" and remove the subjectivity of whether or not an injury is serious. Two commenters asked for the value of defining "Serious Injury" (that is, why does FTA want to collect this information and how would it enhance overall safety). One commenter recommended that FTA remove this definition from all of its safety rules.

Response: Through the Safety Assurance section of today's rule (49 CFR 673.27), FTA requires each operator of a public transportation system to develop a process for conducting investigations of safety events to identify causal factors. FTA defines the word "Event," to mean an "Accident, Incident, or Occurrence," and FTA defines "Accident" to mean, among other things, "a report of a serious injury to a person." To provide guidance to the industry on this term, FTA defined "Serious Injury" in its safety rules, including its new SSO rule at 49 CFR part 674. FTA is adopting the definition of "Serious Injury" from the new SSO rule to ensure consistency throughout FTA's regulatory framework for safety.

FTA has addressed comments regarding its proposed definition of "Serious Injury" in the final SSO rule at 49 CFR part 674 (https://www.gpo.gov/ fdsvs/pkg/FR-2016-03-16/pdf/2016-05489.pdf) and in its responses to the definition of "Accident," above. FTA acknowledges that a transit agency may have difficulty ascertaining a precise type of injury due to medical privacy laws, such as HIPPA. FTA does not expect transit agencies to violate these laws in order to obtain the information needed to determine whether an injury is serious, and it does not expect transit agencies to request the medical records of individuals involved in safety Events that may be classified as Accidents resulting in Serious Injuries. Nor does FTA expect transit agency staff to undergo medical training in order to determine whether an injury meets the threshold of "serious." Instead, FTA expects safety personnel to exercise a common sense approach when evaluating injuries. As several commenters noted, some injuries may be readily known or observable at the scene of an event, in which case, a transit agency may make a determination as to whether an injury is serious. Other injuries may not be apparent until the individual undergoes a medical examination, in which case the injury would be deemed "serious" only if a transit agency becomes aware that the injury meets the threshold for seriousness. FTA believes that a transit agency may utilize these approaches when determining the seriousness of an injury, and it does not believe that it needs to reconcile the definition of "Serious Injury" with other laws.

Given the ability of transit agencies to make observations at the scenes of safety events and to evaluate data and information collected at these scenes, FTA does not believe that any burdens of this rule are unreasonable. FTA does not expect transit agencies to monitor local hospitals or contact individuals involved in safety events within the seven day period to determine if the individuals were hospitalized for more than 48 hours. FTA is not requiring doctors to respond to every safety Event that has the possibility of being classified as an Accident to triage the situation and determine whether the event meets the definition of an Accident, and FTA is not requiring transit agencies to hire medical personnel. In today's rule, FTA is requiring transit agencies to develop a

process for conducting safety investigations.

5. Accountable Executive

Comments: FTA received numerous comments regarding its proposed definition of "Accountable Executive." Several commenters provided input on the definition of "Accountable Executive" as it relates to "Chief Safety Officer." One commenter stated that, according to the proposed rule, the Accountable Executive is responsible for implementing and maintaining the SMS; however, this should be a primary responsibility of the Chief Safety Officer. Another commenter asked whether an Accountable Executive would experience a conflict of interest if he or she also serves as the Chief Safety Officer or SMS Executive, as allowed under proposed 49 CFR 673.23(d)(2), because the duties also involve operational, financial, and other responsibilities that may be in conflict with safety responsibilities.

Several commenters recommended that FTA clarify in the final rule that State officials are not "Accountable Executives" unless the State is a transit operator, and if so, only with respect to the State's activities as a transit operator. Several commenters asked whether the Accountable Executive is the chief elected official, such as a county executive or mayor, in cases where the transit operator is a county or city government. A transit agency, with a general manager who is responsible for the day-to-day aspects of the transit system and a chief administrator who is responsible for the administrative aspects of the organization, asked how it would designate a single Accountable Executive who meets all of the criteria

of 49 CFR part 673.

A few commenters expressed concerns about the overlapping and burdensome responsibilities of the Accountable Executive, which may not allow for sufficient attention to safety. Several commenters said the proposed definition may give an elected official or board chair the designation of an Accountable Executive despite serving at a policy, rather than an operational, level. A transit agency argued that the proposed definition is ambiguous and inconsistent with the proposed National Public Transportation Safety Plan, and some definitions state that the Accountable Executive is in charge of an asset management plan, while other areas omit this requirement. One commenter asserted that the job duties of planning staff are inherently much different from maintenance staff activities, and staff should report to their respective managers instead of a

single executive. Similarly, a commenter stated that, in some instances, a transit agency's reporting structure is shaped by State or local laws to promote a separation of duties and financial checks and balances, and these important governmental tenets should not be disrupted by the new safety requirements. Several commenters suggested that the definition of Accountable Executive may not be applicable in some nontraditional transit agency hierarchies.

Several commenters suggested that the Accountable Executive should be a general manager, president, or equivalent officer who is responsible for safety, asset management, and human resources, but not have full control over the budgeting process. Another commenter stated that that proposed definition may be inappropriate because having one Accountable Executive for SMS, the asset management plan, and the safety plan is ineffective because the Accountable Executive should be represented by different individuals for each regulatory program. The commenter recommended that FTA define an Accountable Executive to be "an individual who is responsible for the Safety Management System and Agency Safety Plan, who shall be required to have a role in the [transit asset management plan] and investment prioritization for the respective agency."

Response: Each transit operator must identify an Accountable Executive within its organization who ultimately is responsible for carrying out and implementing its safety plan and asset management plan. And to be clear, a State that drafts a plan on behalf of another recipient or subrecipient is not the Accountable Executive for those

transit operators.

An Accountable Executive should be a transit operator's chief executive; this person is often the president, chief executive officer, or general manager. FTA understands that at many smaller transit operators, roles and responsibilities are more fluid. However, FTA believes that, even in circumstances where responsibilities are either shared or delegated, there must be one primary decision-maker who is ultimately responsible for both safety and transit asset management. It is a basic management tenet that accountabilities flow top-down. Therefore, as a management system, safety and transit asset management require that accountability reside with an operator's top executive.

FTA received numerous comments on its proposed definition of "Accountable Executive" in its rulemaking on transit asset management, and FTA directs readers to the final Transit Asset Management rule at 49 CFR part 625 for further information (https:// www.gpo.gov/fdsys/pkg/FR-2016-07-26/ pdf/2016-16883.pdf).

6. Chief Safety Officer

Comments: One commenter agreed with FTA that a Chief Safety Officer should not serve in other service, operational, or maintenance capacities. Several commenters agreed with FTA's proposal to allow Section 5310, Section 5311, and small public transportation providers to designate as the Chief Safety Officer a person who also undertakes other functions. Several commenters asked FTA to clarify the term "adequately trained."

One commenter expressed concern that FTA may be assuming that any rail transit agency is large enough to merit its own Chief Safety Officer with no additional operational or maintenance responsibilities, indicating that this requirement is burdensome because a rail transit agency would have to hire or contract a separate Chief Safety Officer for a limited role. The commenter suggested that FTA should permit an exemption for small rail transit agencies similar to the exemption for small public transportation providers to resolve this concern. This commenter also asked FTA to clarify whether a Chief Safety Officer has to be in the direct employ of a rail transit agency and whether he or she could be a parttime employee.

A commenter stated that FTA has proposed, but not promulgated, training rules for SSOA managers, Federal employees, and transit agency staff who are responsible for safety oversight, and argued that these training requirements also should apply to a Chief Safety Officer prior to designation by the Accountable Executive.

One commenter stated that the terms "Chief Safety Officer" and "Safety Officer" are inconsistently used, and the term "Safety Officer" was not defined in the NPRM. To rectify this inconsistency, the commenter, who concluded that it is implied that the Safety Officer is the Chief Safety Officer, suggested that FTA should replace the term "Safety Officer" with "Chief Safety Officer."

Response: FTA appreciates the support from commenters regarding its proposed definition of "Chief Safety Officer." Given the different sizes of transit operators, and given the varying operating environments of transit systems across the nation, FTA is deferring to each transit operator to determine the level of training that is adequate for their Chief Safety Officer.

FTA disagrees with the commenter who suggested that a Chief Safety Officer at a rail transit agency should be able to have multiple roles within the organization. Given the more complex operating environments of rail transit systems and the increased safety risks in these environments, FTA will not allow the Chief Safety Officers for rail transit agencies to have additional operational and maintenance responsibilities; it is necessary to have a single individual wholly dedicated to ensuring safety. FTA believes that this role should be a full-time responsibility at rail transit agencies, unless a rail transit agency petitions FTA to allow its Chief Safety Officer to serve multiple roles given administrative and financial hardships with having a single, dedicated, and full-time Chief Safety Officer.

Finally, FTA notes that all references to the term "Safety Officer" in the NPRM were intended to mean the term "Chief Safety Officer."

7. Operator of Public Transportation System

Comments: One commenter suggested that an "Operator of a Public Transportation System" should be "any organization, agency, or company that operates, or contracts someone to operate, any mode of transportation that is used by the general public in a defined city, State, or region."

Response: The proposed rule defines "Operator of a Public Transportation System" as "a provider of public transportation as defined under 49 U.S.C. 5302(14), and which does not provide service that is closed to the general public and only available for a particular clientele." Given that FTA is deferring action regarding the applicability of this rule to Section 5310 recipients, FTA has changed this definition in the final rule to be "a provider of public transportation as defined under 49 U.S.C. 5302(14)." The additional language—"and which does not provide service that is closed to the general public and only available for a particular clientele"—is not needed since the rule is not applicable to Section 5310 recipients at this time. FTA believes that the proposed definition is sufficiently broad to encompass the categories of transit providers referenced in the commenter's definition. FTA does not agree that the definition needs to specify that an operator provide service in a defined city, State, or region.

8. Rail Transit Agency

Comments: The proposed rule defines a "Rail Transit Agency" as "any entity that provides services on a rail fixed guideway public transportation system." One commenter asked FTA to clarify whether the proposed definition applies equally to a public transit operator and a contracted private firm that operates and maintains services on a rail fixed guideway public transportation system.

Response: This rule applies to any operator of a public transportation system that receives Federal financial assistance under 49 U.S.C. Chapter 53, including rail transit operators that receive FTA funds and are not regulated by FRA, unless the operator only receives Section 5310 and/or Section 5311 funds. The application of this rule extends to contracted private firms that operate public transportation and receive FTA funds, but it does not extend to private contractors that provide service that is not public transportation.

9. Performance Target, Safety Performance Target, and Performance Criteria

Comments: One commenter remarked that the proposed definition for "Performance Target" needs clarity. Another commenter stated that FTA should consider deleting the proposed definition for "Performance Target," because the proposed definition for "Safety Performance Target" is more appropriate for this safety-related rule. This commenter also suggested revising the definition of "Safety Performance Target" to "a specific level of measurable performance for a given safety performance criteria over a specified timeframe."

FTA proposed to define "Performance Criteria" as "categories of measures indicating the level of safe performance within a transit agency." One commenter stated that this definition is confusing and possibly inconsistent with the proposed National Public Transportation Safety Plan. The commenter stated that the terms "Criteria" and "Measures" appear to be synonymous, and proposed the following definition for "Performance Criteria": "Categories of safety performance measures that focus on the reduction of safety events, both for the public who use or interface with the rail system, and employees who operate and maintain the system."

Response: As appropriate, FTA has incorporated into this rule definitions that appear in other rulemakings undertaken pursuant to 49 U.S.C. 5329 and 5326, as well as the final joint FHWA/FTA Planning Rule which was published May 27, 2016 (see https://www.gpo.gov/fdsys/pkg/FR-2016-05-27/pdf/2016-11964.pdf). Accordingly, FTA

has revised the definition of "Performance Target" and added the definition of "Performance Measure" to match the definitions used in the joint FHWA/FTA Planning rule and FTA's Transit Asset Management rule.

To avoid redundancy, FTA is deleting the definition for "Safety Performance Target" and keeping the definition of "Performance Target," since these terms are one and the same for purposes of this rule.

FTA had to reconcile the use of similar terms throughout its statutory authorizations for safety and asset management, including the terms "criteria" and "measures." Although Congress used two different terms throughout 49 U.S.C. Chapter 53, it intended these terms to be synonymous. In the NPRM, FTA proposed to define "Performance Criteria" to mean "categories of measures indicating the level of safe performance within a transit agency," but to eliminate confusion in this final rule, FTA removes that term, replaces it with the term "Performance Measure," and incorporates the definition of "Performance Measure" as used in FTA's Transit Asset Management rule. Consequently, FTA uses the term "Performance Measure," in the place of "Performance Criteria," throughout this final rule.

10. Small Public Transportation Provider

Comments: The proposed rule defines "Small Public Transportation Provider" as "a recipient or subrecipient of Urbanized Area Formula Program funds under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in revenue service and does not operate a rail fixed guideway public transportation system."

Several commenters requested FTA to clarify that the "100 buses in revenue service standard" applies only to recipients of Section 5307 funds, and not recipients of Section 5310 or 5311 funds. One commenter asked whether the threshold of 100 vehicles in revenue service refers to total revenue fleet vehicles, peak vehicles, or something else. Another commenter that operates commuter rail service regulated by FRA, but has fewer than 100 buses in revenue service, asserted that they met the definition of a "Small Public Transportation Provider." The commenter stated it posed this assertion to FTA during a webinar for this rulemaking on March 2, 2016, and it requested that FTA clarification the application of the rule to its scenario.

A couple of commenters remarked that the proposed definition for "Small

Public Transportation Provider" differed between related rulemakings and notices, specifically the TAM proposed rule and FTA's Circular 9030.1E. Commenters noted that the TAM rule's reference to "in revenue service" is a typical definition in the industry and should be adhered to across all proposed rulemakings.

Other commenters suggested that the definition include providers with "100 or fewer fixed-route vehicles," or be based on the service area's population rather than the number of buses. Additionally, one commenter suggested that vanpool fleets that are not open to the general public should be counted as revenue service vehicles.

Several commenters noted that significant differences exist between rail transit operators, large bus operators, and smaller operators, particularly in the ways in which they conduct business and in the rate of accidents and the consequences of those accidents. One commenter stated that the categories in the proposed rule are too broad and rigid and could have unintended consequences for small operators. The commenter remarked that the rigidity of a "two-tier system" could cause a Section 5307 recipient, with under 100 vehicles, to have their oversight provided by the State. Another commenter stated that the two-tier system does not take into account a Section 5311 recipient that may serve multiple counties with over 100 vehicles. The commenter remarked that there is no definition for this type of system within the "tiers" and that the Section 5311 recipient might be bumped into a higher category. One commenter suggested adding a third tier for systems operating fifty or fewer vehicles and no rail fixed guideway public transportation service to provide States with the opportunity to implement SMS scalable to the size and complexity of the transit organization.

Response: FTA appreciates the comments that it received regarding its proposed definition for "Small Public Transportation Provider." FTA agrees with the commenters who suggested that FTA align this definition with the definition in the final TAM rule, and FTA agrees with the commenters who suggested that FTA create the threshold for Small Public Transportation Providers based on vehicles utilized in peak revenue service, as opposed to revenue service in general, as peak revenue service is a threshold commonly used in the transit industry. Therefore, in today's final rule, FTA defines "Small Public Transportation Provider" to mean "a recipient or subrecipient of Federal financial

assistance under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in peak revenue service and does not operate a rail fixed guideway public transportation system."

11. Requests for New Definitions

Comments: One commenter requested that FTA add new definitions for the term "safety performance assessment." One commenter recommended that FTA clarify whether the term "Public Transportation Vehicle" includes rail, bus, paratransit, maintenance, and nonrevenue vehicles. Several commenters recommended that FTA define the term "Transit Provider" as follows: "A State is not considered to be a transit provider by virtue of passing on funds to subrecipients under 49 U.S.C. 5310, 5311, or 5339, administering these programs, developing and implementing a TAM plan, or safety plan or certifying a safety plan, or taking any other steps required of a State by Chapter 53 of title 49, United States Code or other Federal statue, or by this or other FTA rules."

Response: For purposes of implementing this rule, FTA does not find it necessary to further define the term "safety performance assessment." Generally, this term refers to a transit agency's evaluation of its success of managing safety risks. To the extent there is any confusion over this term, FTA will provide technical assistance.

FTA notes that a public transportation vehicle may include rail, bus, paratransit, maintenance, and non-revenue vehicles, as the term is utilized in the definition of "Accident."

Finally, FTA did not propose to define the term "Transit Provider" in the NPRM, and FTA believes that the term is sufficiently descriptive and does not need to be defined in this rule.

C. General Requirements

Comments: Several commenters provided high-level feedback regarding the general requirements for PTASPs as proposed in 49 CFR 673.11. One commenter suggested that FTA should clearly emphasize that these elements are minimum requirements and that a transit agency should be able to enhance its SMS and incorporate tools and best practices that are proven to be effective, particularly given the adaptability, scalability, and flexibility of SMS.

One commenter asserted that the combination of the general requirements for each written safety plan, along with the requirements to "establish SMS processes," results in a lack of clarity regarding the required contents of the actual document that a transit agency would consider to be its safety plan. This commenter stated that FTA should

provide at least the same degree of specificity with regard to the required contents of a transit agency's written safety plan that FTA provided for SSPPs under the former SSO rule at 49 CFR part 659.

Response: As discussed throughout today's final rule, SMS is scalable and flexible, and it can be adapted to any transit agency's unique operating environment. The requirements in the rule provide the skeleton framework for safety plans, and FTA encourages transit agencies to incorporate tools and best practices that effectively mitigate and eliminate safety risks throughout their systems.

To be clear, each written safety plan must include the documented processes and procedures related to SMS, and the written plan must include each of the other requirements as outlined in the rule. FTA intentionally drafted broad, non-prescriptive requirements for SMS in an effort to develop a safety framework that could fit within the thousands of unique transit operating environments across the nation.

1. Role of the Accountable Executive

Comments: Pursuant to FTA's proposed provisions at 49 CFR 673.11(a)(1), each transit agency's Accountable Executive must sign the agency's safety plan and subsequent updates thereto. One commenter supported this provision and asserted that the requirement is essential for SMS and for maintaining a positive safety culture. Another commenter agreed that the Accountable Executive with budgetary authority should review and approve the safety plan.

A couple of commenters asked whether the Accountable Executive must be the same individual for purposes of approving the agency's safety plan and the agency's transit asset management plan, and they asked whether the Accountable Executive must be the individual explicitly "responsible for implementing SMS." These commenters also inquired about the Accountable Executive's role for municipal government agencies, and they asked whether the head of a city's department of transportation, the head of a city's department of public works, or a city manager may serve as the Accountable Executive for a municipal government agency, as opposed to a city's mayor.

Response: As a preliminary matter, FTA distinguishes the role of the Accountable Executive from the role of a Board of Directors, or an Equivalent Authority. Pursuant to 49 CFR 673.11(a)(1), the Accountable Executive must sign the safety plan; the Board of

Directors or an Equivalent Authority must approve the safety plan in accordance with 49 U.S.C. 5329(d)(1)(A).

Given the varying sizes and natures of transit systems, FTA defers to those systems in their designation of an Accountable Executive, so long as that single individual has the ultimate responsibility and accountability for the implementation and maintenance of the SMS of a public transportation agency; responsibility for carrying out the agency's transit asset management plan; and control or direction over the human and capital resources needed to develop and maintain both the agency's public transportation agency safety plan and the agency's transit asset management plan. For municipal government agencies, that individual could be a county executive or a mayor, or it could be the head of a city's department of transportation, the head of a city's department of public works, or a city manager. FTA has offered this nonexhaustive list of examples of Accountable Executives for illustrative purposes only. And while many individuals within a transit agency may be responsible for "implementing" SMS, the Accountable Executive is the individual with the ultimately responsibility for SMS implementation at the agency.

2. Approval of a Public Transportation Agency Safety Plan

Comments: Pursuant to FTA's proposed provisions at 49 CFR 673.11(a)(1), each transit agency would be required to have its safety plan, and subsequent updates thereto, approved by the agency's Board of Directors, or an Equivalent Authority. One commenter supported this provision, indicating that this activity is essential for SMS and for maintaining a positive safety culture.

Several commenters asserted that the agency's Accountable Executive, not the Board of Directors, would be the more appropriate entity to approve the safety plan. These commenters stated that a Board of Directors, which can consist of limited-term elected officials, are not subject to the same training requirements as the Accountable Executive, and do not have the operational knowledge and expertise suitable for the review and approval of a safety plan. One of these commenters suggested that the Accountable Executive have top-level ownership of the safety plan, with a stipulated responsibility to educate and report to the Board of Directors on the agency's safety program.

Several commenters asked questions about the implementation of this

provision for agencies that lack Boards of Directors. A couple of commenters asked if transit agencies can request FTA to approve their "Equivalent Authorities," or whether they must wait for an FTA oversight review to determine whether their Equivalent Authorities are consistent with the rule. A couple of commenters had specific questions regarding the adequacy of an Equivalent Authority. One example involved a streetcar being owned by a city, but being operated and maintained by a non-profit organization with its own Board of Directors. Another example involved a State Department of Transportation which does not have a Board of Directors, but instead, has an Administrator/CEO. One commenter asked FTA to provide a clear example of an "Equivalent Authority" if a recipient does not have a Board of Directors. Similarly, another commenter asserted that a State may have difficulty identifying an Equivalent Authority because a subrecipient may be a parish or county that does not necessarily have a Board of Directors. Another commenter recommended that an Equivalent Authority should have a thorough knowledge of a transit agency's daily operations and the authority to obtain operational and safety data so that it could provide safety oversight.

One commenter asked about the measure of "approval" for the Board of Directors, and inquired as to what that approval would denote in terms of

safety responsibility.

Another commenter observed that a transit agency with rail and bus operations must have its safety plan approved by the SSOA for purposes of its rail operations, and suggested that FTA would have to approve the safety plan for purposes of its bus operations. This commenter expressed concern that, unless there are very clear guidelines for the review and approval of the safety plans, there is the potential for conflicting views and approvals, including approval of one operation and not the other.

Response: FTA appreciates concerns from commenters indicating that members of a transit agency's Board of Directors may not be fully educated in safety; however, through the statutory provisions of 49 U.S.C. 5329(d)(1)(A), Congress required each transit agency's Board of Directors, or an Equivalent Authority, to approve the agency's safety plan. Through the Safety Management Policy provisions of 49 CFR 673.23 and the Safety Promotion provisions of 49 CFR 673.29, each transit agency is required to identify individuals who are responsible for

safety in their organization and to ensure that those individuals are adequately trained, including staff and executive leadership, and this requirement should extend to a transit agency's Board of Directors.

If a transit agency does not have a Board of Directors, then an Equivalent Authority may approve its safety plan. An Equivalent Authority is an entity that carries out duties similar to that of a Board of Directors, including sufficient authority to review and approve a safety plan. For example, an Equivalent Authority could be the policy decision-maker/grant manager for a small public transportation provider; the city council and/or city manager for a city; a county legislature for a county; or a State transportation commission for a State. Given the varying sizes and organizational structures of the thousands of recipients and subrecipients throughout the country, FTA is not providing a prescriptive definition of this term, and it is deferring to each transit agency to identify who would be an Equivalent Authority for its system. FTA intends its list of examples to be non-exhaustive and illustrative only.

The approval of the safety plan should mean that the Board of Directors or the Equivalent Authority accepts the safety plan as satisfactory, that the safety plan complies with each of the requirements of this rule, and that the safety plan effectively will guide the transit operator with the management of safety risks.

Finally, to clarify, FTA does not intend to collect and "approve" safety plans. FTA intends to ensure that transit agencies comply with this rule by reviewing their safety plans through FTA's existing Triennial Reviews and State Management Reviews. Through these oversight processes, FTA may collect various documents, including safety plans, to ensure compliance with this part, but FTA will not provide regular "approvals" of the plans. SSOAs, however, must approve the safety plans of rail fixed guideway

3. Documentation of SMS Processes and Activities

public transportation operations within

their jurisdictions.

Comments: Pursuant to FTA's proposed provisions at 49 CFR 673.11(a)(2), each transit agency would be required to document its processes and activities related to SMS in its safety plan. One commenter sought clarity regarding whether the safety plan must detail the processes and activities, or just indicate that such processes and activities exist. Another commenter

asked which documents should be included in the safety plan, specifically whether the safety plan should include documents that are generated by the results of ongoing SMS activities, or only those documents which formally present a description of SMS processes.

Response: Each safety plan must include documented SMS processes; it is not sufficient to merely indicate in the safety plan that SMS processes exist. Through the practice and implementation of SMS, each transit agency may generate data and other documentation, but the safety plan itself must document each of the processes as outlined in this rule. FTA is providing discretion to each transit agency to decide for itself whether it will incorporate processes and documented activities beyond those required in today's final rule.

4. Safety Performance Targets

Comments: Pursuant to FTA's proposed provisions at 49 CFR 673.11(a)(3), each transit agency would be required to identify in its safety plan performance targets based on the safety performance measures that FTA establishes in the National Public Transportation Safety Plan. One commenter supported FTA's proposed list of safety performance measures as outlined in the National Public Transportation Safety Plan, but several commenters recommended that FTA expand the list of performance measures. One commenter recommended that FTA reduce its proposed list of safety performance measures to align with the safety outcomes that transit agencies currently report to NTD. One commenter stated that the proposed definition of "Performance Criteria" is confusing and inconsistent with the National Public Transportation Safety Plan. The commenter stated that the terms "Criteria" and "Measures" are synonymous, and proposed the following alternate definition: "categories of safety performance measures that focus on the reduction of safety events, both for the public who use or interface with the rail system, and employees who operate and maintain the system." Several commenters requested that FTA provide agencies with additional guidance on the four basic safety performance measures.

One commenter asked whether the safety plan must contain specific quantitative performance targets for all performance measures. This commenter stated that specific quantitative targets would pose challenges for transit agencies and that all targets should be

broad and not static to allow agencies to adjust their targets as new information dictates. Several commenters requested FTA to allow transit agencies to update and revise their safety plans if FTA alters or adjusts performance measures.

Response: FTA appreciates the comments that it received regarding its proposed safety performance measures; however, the proper vehicle for addressing these comments is through the notice and comment process tied to FTA's proposed National Public Transportation Safety Plan (RIN 2132-ZA04). The National Public Transportation Safety Plan will identify FTA's safety performance measures, not today's rule for Public Transportation Agency Safety Plans. The Public Transportation Agency Safety Plan rule only requires transit agencies to set performance targets based on the performance measures established in the National Public Transportation Safety Plan. FTA will address all of the comments related to safety performance measures in the National Public Transportation Safety Plan, including the above-referenced comments that were directed to this rulemaking.

FTA notes that in the NPRM for this rule, FTA used the term "Performance Criteria," which it proposed to define as "categories of measures indicating the level of safe performance within a transit agency." FTA used this term because the language of 49 U.S.C. 5329 uses the term "Performance Criteria." Other parts of FTA's authorizing statute, such as the Transit Asset Management provisions of 49 U.S.C. 5326, use the term "Performance Measures." FTA believes that Congress intended the terms "Performance Criteria" and "Performance Measures" to be synonymous. To eliminate confusion over distinctions between these terms and to ensure consistency with the use of these terms throughout FTA's programs, FTA has removed the term 'Performance Criteria' from today's final rule and replaced it with the term "Performance Measure."

Finally, in accordance with the statutory requirements of 49 U.S.C. 5329(d)(1)(E), each transit agency must include in its safety plan, "performance targets based on the safety performance criteria and state of good repair standards." These targets must be specific numerical targets set by transit agencies themselves. FTA emphasizes, however, that the safety plan is intended to be a living document that evolves over time. FTA expects transit agencies to modify their safety plans, and to adjust their performance targets, as they collect data and implement SMS. Indeed, the performance targets

may change from year to year, or more frequently, as safety data may necessitate.

5. Future Requirements in FTA's Public Transportation Safety Program and National Public Transportation Safety

Comments: One commenter requested FTA to provide guidance on what it means to "address" the requirements and standards in its Public Transportation Safety Program and National Public Transportation Safety Plan. Another commenter expressed concern that FTA has not established formal standards for these requirements, and requested FTA to establish minimum measures and targets for safety performance and improvement.

Response: In today's final rule, FTA is requiring each transit agency to address—more specifically, to ensure that it is complying with—all applicable requirements and standards as set forth in FTA's Public Transportation Safety Program at 49 CFR part 671 and the National Public Transportation Safety Plan. In particular, each transit agency must identify safety performance targets based on the performance measures that FTA establishes in the National Public Transportation Safety Plan. Additionally, FTA encourages transit agencies to adopt any voluntary minimum safety performance standards established in the National Public Transportation Safety Plan, until mandatory standards are established, in which case each transit agency must fully comply with those safety performance standards. To the extent that FTA amends its Public Transportation Safety Program Rule or the National Public Transportation Safety Plan in the future, FTA expects each transit agency to amend its safety plan, as appropriate.

6. Process and Timeline for Annual Review and Update

Comments: One commenter asked FTA to clarify if the timeline for the annual review process is determined by each transit agency, or whether there is a particular date by which an annual review and update is required.

Several commenters disagreed with the proposed requirement that the plans be updated annually. Some commenters suggested that safety plans only need to be updated every two years because the requirement for an annual update of safety plans is excessive and burdensome. Several of these commenters asserted that if annual action is needed, an annual review and status report would be less resource intensive. A few commenters suggested

that safety plans need only to be updated every two years, unless there is a significant policy or change in condition (such as a fatality) that warrants a change. Another commenter recommended the same approach, but with updates required every three years rather than two years. One commenter suggested alternative review schedules ranging from every two years to every five years. One commenter suggested that organizations which meet various criteria should be placed on a five year review plan and they should be required to submit any requested updates to policies for review and approval.

One commenter asserted the review requirement should be consistent with FTA's proposed rule for Transit Asset Management Plans, which would require each transit agency to update its Transit Asset Management Plan at least once every four years. Additionally, this commenter suggested that the rule should require an update of a safety plan in any year when risk assessments result in the need for substantial mitigation, or if there are significant changes to asset inventory, condition assessments, or investment

prioritization.

A couple of commenters asked about the required annual update as it may relate to a rail transit agency's SSPP annual reviews. A commenter asked whether the process for conducting annual reviews would likely be similar to the SSPP annual reviews, including requirements that an Accountable Executive would perform the review and that a transit agency document all updates and revisions. A commenter suggested that the proposed requirement to conduct an annual review and update the safety plan, as needed, differed from the requirement to conduct a formal annual internal audit of the SSPP.

A commenter expressed concern with FTA's decision to publish the National Public Transportation Safety Plan with no schedule for revision, which would cause transit agencies to continuously update their safety plans to coincide with any changes in FTA guidance documents. This commenter further encouraged FTA to define prescriptive elements of the annual review and update process to better guide agencies.

Response: Pursuant to the statutory provisions of 49 U.S.C. 5239(d)(1)(D), each operator of a public transportation system must develop a safety plan which includes "a process and timeline for conducting an annual review and update of the safety plan." In light of this statutory language, today's final rule requires each transit agency to establish a process and timeline for conducting a review and update of its

safety plan, and this review and update must occur at least annually. 49 CFR 673.11(a)(5).

Given the diversity in transit systems across the country, and given each transit agency's unique operating environment, FTA is deferring to each transit agency to determine, for itself, the frequency of its safety plan reviews and updates each year, and the process for doing so. Each transit agency must certify compliance with these requirements through its annual Certifications and Assurances to FTA.

FTA disagrees with the commenters who proposed that the annual review period for the safety plans be changed to a less frequent time period, such as two years, three years, four years, or five years. The statutory provisions of 49 U.S.C. 5329(d)(1)(D) do not provide that latitude. Notwithstanding the statute, as a matter of a best safety practice, FTA believes that each transit agency should annually review its process for hazard identification and risk analysis in an effort to prevent safety events. As a transit agency collects data through the hazard identification and risk analysis processes, the transit agency should be evaluating its safety performance targets to determine whether they need to be changed, as well.

FTĂ agrees with the commenter who suggested that along with an annual review, a transit agency should update its safety plan at any point when risk assessments result in the need for substantial safety mitigation, or if there are significant changes to asset inventory, condition assessments, or investment prioritization.

Regarding the annual reviews of SSPPs, FTA notes that under its new public transportation safety program, the requirements for SSPPs under the former regulatory provisions of FTA's SSO rule at 49 CFR part 659 have been eliminated. Today's requirement for a PTASP under 49 CFR part 673 replaces the old requirement for an SSPP under 49 CFR part 659. Therefore, annual reviews of the PTASP now will be required, and SSPPs will become obsolete for rail transit agencies one year after the effective date of this final rule.

Finally, regarding the National Public Transportation Safety Plan, FTA will update the National Public Transportation Safety Plan when it believes it is necessary to do so, based on safety needs in the public transportation industry. FTA notes that it must make any changes to the National Public Transportation Safety Plan through the public notice and comment process, and the transit industry will have the opportunity to

provide input on any changes to this document. Furthermore, FTA believes that changes to the National Public Transportation Safety Plan will not necessarily cause transit agencies to update their PTASPs. Currently, the National Public Transportation Safety Plan and the Public Transportation Agency Safety Plans are linked through the requirements for performance targets in agency safety plans based on the performance measures in the National Public Transportation Safety Plan.

7. Emergency Preparedness and Response Plans

Comments: Pursuant to the proposed provisions of 49 CFR 673.11(a)(6), each rail transit agency would be required to include an emergency preparedness and response plan in its safety plan. Although a commenter noted that there is no statutory language in 49 U.S.C. 5329 which requires emergency preparedness and response plans, the commenter agreed that this type of plan is important and should be included in safety plans. One commenter supported the requirement that transit agencies develop a plan for the delegation of responsibilities during an emergency, but encouraged FTA to include in the final rule a requirement that ensures transit agencies provide adequate training for workers responsible for tasks during emergencies.

Two commenters suggested that FTA should provide transit agencies with the option of separating their safety plans and their emergency preparedness and response plans, developing them as two separate documents. One of these commenters suggested that these documents are fundamentally different and the emergency preparedness and response plan contains information that should not be widely distributed. One of these commenters suggested that some transit agencies that have not previously complied with 49 CFR part 659 may have difficulty developing a robust emergency preparedness and response plan. This commenter also stated that FTA should take into consideration the time and resources needed to develop a comprehensive emergency response plan by publishing templates for these plans, offering assistance to those transit agencies developing them for the first time, and extending the implementation deadline for this final rule. Another commenter requested clarification regarding whether this final rule would require a System Security Plan and an emergency preparedness and response plan to be separate documents.

One commenter suggested that FTA revise the rule to allow a transit agency to include or reference the emergency

preparedness and response plan in its safety plan. This commenter said this revision would be consistent with the intent of FTA in the Section-by-Section Analysis portion of the NPRM which states that this section would require that each rail transit agency "include, or incorporate by reference" the emergency preparedness plan in its safety plan.

Another commenter asked FTA to

Another commenter asked FTA to clarify the relationship between the emergency preparedness and response plans required in this rule to the emergency preparedness and response plans required in the former SSO provisions of 49 CFR 659.19(k).

Response: Although the statutory provisions of 49 U.S.C. 5329 do not require emergency preparedness and response plans, FTA's State Safety Oversight Rule historically has required rail transit agencies to have emergency preparedness and response plans as part of their SSPPs. Since rail transit agencies already have these plans in place, FTA is carrying over the requirement for those plans into today's rule. FTA's intent is to make transit safer, not to make transit less safe by eliminating historical requirements that have proven to be effective. FTA acknowledges the potential burdens on transit agencies that do not have these plans in place, and therefore, FTA only is requiring emergency preparedness and response plans from rail transit agencies, which should already have them in place. FTA agrees with the commenter who suggested that these plans are important, as recent safety events have demonstrated the need and utility of emergency preparedness and response plans, particularly for rail transit systems.

FTA agrees that rail transit agencies should develop plans to include the delegation of responsibilities during an emergency. FTA is deferring to transit agencies on how to document their emergency preparedness and response plans, and FTA will allow transit agencies to combine, include, incorporate by reference, or separate their emergency preparedness and response plans and their safety plans.

FTA is issuing templates and guidance for safety plans concurrently with the issuance of today's final rule. FTA intends to develop guidance specific to emergency preparedness and response plans in the future. FTA also will provide technical assistance to rail transit agencies that are modifying or developing emergency preparedness and response plans.

FTA notes that it no longer is requiring System Security Plans as previously required for rail transit agencies under the former regulatory provisions of 49 CFR part 659—the responsibility for the oversight of transit security resides with the U.S. Department of Homeland Security's Transportation Security Administration (TSA). However, to the extent that a transit agency has a security plan, FTA will allow a transit agency to incorporate the security plan into its safety plan, if the transit agency desires.

In light of the above, FTA is revising the language in today's final rule to match the intent referenced in the NPRM's Section-by-Section Analysis, which states that each rail transit agency is required to "include, or incorporate by reference" an emergency preparedness and response plan in its safety plan. FTA directs readers to its SSPP-PTASP Crosswalk interim guidance document for further information on the relationship between SSPPs and PTASPs (https:// www.transit.dot.gov/sites/fta.dot.gov/ files/docs/PTSP NPRM SSPP Side by *Side.pdf*). Additional guidance will be forthcoming, and FTA will post it on its website (see https:// www.transit.dot.gov/regulations-andguidance/safety/transit-safety-oversighttso).

8. Multiple Modes of Transit Service

Comments: A few commenters supported FTA's proposed flexibility for transit agencies to develop one safety plan for all modes of transit. A couple of commenters stated that they would develop one safety plan for all modes. One of these commenters stated that updating and monitoring several plans is unrealistic and increases the workload and approval processes. This commenter also asked if FTA would issue rules specific to locally operated transit systems.

A couple of commenters encouraged the use of one safety plan that encompasses all modes of transportation. A commenter stated that if a transit agency develops one safety plan for all transportation modes, then that transit agency should identify those portions of its system that are regulated by another Federal entity and include any additional requirements from those Federal entities in the safety plan.

One commenter suggested that safety plans for all transit modes creates a difficult regulatory process for SSOAs, since SSOAs have regulatory authority over the rail mode only. This commenter recommended that FTA require rail transit agencies to develop a separate plan for rail, since the safety plan must be submitted to the SSOA for review and approval. Alternatively, the commenter requested that FTA include specific processes for SSOAs and rail

transit agencies when dealing with a single plan covering multiple modes.

Response: FTA agrees with and appreciates the commenters who would like the flexibility to either have one safety plan or multiple safety plans for multiple modes of transit service. As FTA stated in the NPRM, it intends to allow flexibility and choice so that transit agencies may draft multiple plans or only one plan, as there are many different sizes and types of transit agencies—a single plan may work better for some agencies, whereas multiple plans for multiple modes of transit service may work better for others (especially the larger transit agencies that have multiple divisions and operate commuter rail, heavy rail, light rail, bus, and other transit modes).

FTA disagrees with commenters who would like to develop a single plan for all modes of transportation service, particularly service that is regulated by another Federal entity, such as FRA. Other Federal regulators may have specific requirements for safety plans that fall under their jurisdiction that may conflict with this final rule. Notably, FRA's statutory and regulatory framework for rail safety provides data protection in safety plans; FTA's statutory and regulatory framework does not. FTA is concerned that combining PTASPs and FRA-regulated safety plans would result in a loss of that data protection for the rail safety covered by FRA. Therefore, FTA will not allow a transit agency to combine its PTASP with a safety plan for service regulated by another Federal agency.

FTA disagrees that SSOAs will have difficulty approving safety plans that address rail and bus service. Indeed, SSOAs have regulatory authority over rail transit service only, and SSOAs should review only the rail components of safety plans. FTA will provide additional guidance and training in the future to assist SSOAs with their review and oversight of PTASPs and SMS.

D. State and Transit Agency Roles

1. Large Transit Agencies

Comments: One commenter recommended that the rule detail the requirements applicable to large transit agencies.

Response: Pursuant to this rule, every operator of a public transportation system—large and small—must comply with each of the requirements outlined in today's final rule, unless the operator only receives Section 5310 and/or Section 5311 funds. All sections and requirements of this rule as outlined in 49 CFR part 673 are applicable to large transit agencies, specifically, rail fixed

guideway public transportation systems and recipients and subrecipients of FTA funds under 49 U.S.C. Chapter 53 that operate more than 100 vehicles in peak revenue service.

- 2. Small Public Transportation Providers, Section 5311 Providers, and Section 5310 Providers
- 2.1. States Must Draft and Certify Safety Plans on Behalf of Small Public Transportation Providers
- 2.1.1. Option for State-Wide or Agency-Specific Safety Plans

Comments: Several commenters responded to FTA's question as to whether FTA should require States to draft a single state-wide plan; individual safety plans for each Section 5310, Section 5311, and small public transportation provider located within that State; or defer to the State's preference. A few commenters recommended that each State should have the flexibility to choose whether the State will develop and certify a single state-wide plan or draft individual safety plans on for each agency. One commenter stated that the State should be required to draft an umbrella plan for more than just "small public transportation providers" and an agency can choose to use that plan or develop their own plan that complies with the overarching plan. Another commenter stated that state-wide plans should be generic and that States should develop an SMS that would be flexible enough to meet the needs of each of the individual transit agencies within their jurisdictions. This commenter also asked what might happen when a transit agency's safety plan differs from another transit agency's safety plan drafted by their State. One commenter suggested a "hybrid" approach whereby the State may draft a single safety plan, and include appendices that incorporate unique situations for certain transit agencies. Another commenter suggested that if a State develops a state-wide plan, then all transit providers should be required to provide copies of their plans and self-certifications to the State.

One commenter asserted that small urban and rural operations likely will be different, and if a State must draft separate safety plans for each transit agency, then this effort will be burdensome. On the other hand, the commenter asserted, if the State drafts only a single safety plan for all transit agencies under this regulatory provision, then the safety plans may be ineffective and meaningless.

In response to FTA's question as to how a single state-wide safety plan could respond to the Safety Risk Management component of SMS (such as the identification of risks and hazards for each unique transit agency), several commenters stated there are already processes in place at State Departments of Transportation that can integrate individual SMS components of Safety Risk Management for small bus public transportation providers to enable the drafting of a state-wide agency safety plan.

Response: To provide maximum flexibility for States and transit providers, FTA is deferring to the States and the small public transportation providers within those States to determine whether each State will draft and certify a single state-wide safety plan for all small public transportation providers or whether it will draft and certify multiple individualized safety plans for each of these transit operators. FTA recommends as a best practice that each State draft and certify individualized safety plans on behalf of each of these small public transportation providers given the inherently unique safety concerns, issues, hazards, and risks for each transit operator. If a State drafts a single state-wide safety plan, then the State must ensure that the plan clearly identifies each transit operator that the plan will cover, the names of the Accountable Executives and Chief Safety Officers, the safety performance targets for each transit operator (and determined in conjunction with each operator), and the hazard identification, risk analysis, Safety Assurance, and other SMS processes for each transit operator (and developed in conjunction with each transit operator).

FTA notes that, in this rule, States are not required to draft and certify safety plans on behalf of transit operators that only receive Section 5310 and/or Section 5311 funds. As discussed above, FTA is deferring regulatory action regarding the applicability of this rule on these operators until a later date.

2.1.2. Drafting and Certifying Safety Plans for Small Section 5307 Providers

Comments: Several commenters suggested that States should not be required to draft and certify safety plans for small Section 5307 providers in large urbanized areas because these providers are not subrecipients of funds apportioned to States, they have a direct funding relationship with FTA, States do not review their grant applications, States do not review their NTD reports, and States do not provide their oversight.

A few of these commenters only supported the requirement that States draft and certify safety plans on behalf of open door Section 5310 and Section 5311 subrecipients. A couple of commenters supported the requirement that a State draft and certify safety plans on behalf of small Section 5307 providers operating 100 or fewer vehicles, as long as the final rule clarifies that the "100 vehicles in revenue service" criteria applies only to Section 5307 recipients, not Section 5310 or Section 5311 recipients.

Response: FTA notes that 49 U.S.C. 5329(d)(3)(B) provides that States may draft or certify safety plans on behalf of "small public transportation providers" that receive Section 5307 funds, even though, for recipients in large urbanized areas, no funding relationship exists between the States and those small Section 5307 recipients. In response to comments and to ensure consistency across FTA's safety rules and Transit Asset Management rule, FTA is defining "small public transportation provider" to mean "a recipient or subrecipient of Federal financial assistance under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in peak revenue service and does not operate a rail fixed guideway public transportation system." A small Section 5307 provider may opt to draft and certify its own safety plan.

FTA notes that it received numerous comments requesting reduced requirements for small public transportation providers. Given their limited resources, FTA believes that a reduction in requirements for small public transportation providers is appropriate, and to that end, FTA eliminated Safety Assurance requirements for all small public transportation providers under 49 CFR 673.27(a).

2.2. Other Comments

Comments: One commenter expressed a concern about potential conflicts of interest regarding the drafting and certifying of safety plans. This commenter stated that if a State drafts and certifies a safety plan on behalf of a transit operator, and if the State is also the grant manager for the transit agency using the safety plan, then the State may monitor compliance with the safety plan that it drafted through grant compliance reviews. The commenter suggested that this situation may create a conflict of interest, similar to the conflict of interest that would arise if an SSOA drafted and certified a safety plan on behalf a rail transit agency subject to its jurisdiction.

One commenter asked whether a small transit provider may continue to use its safety plan drafted by its State if it grows to a size where it no longer would be considered small. In this scenario, the commenter asked how much time the transit provider would have to draft and certify a new safety plan.

One commenter recommended that FTA clarify the definition of the term "State" so that SSOAs would not draft or develop a transit agency's safety plan if a conflict of interest exists. Additionally, the commenter suggested adding the following language at the end of section 49 CFR 673.11: "the State Safety Oversight Agency cannot be involved in the development of the Public Transportation Agency Safety Plans they are charged with overseeing."

Response: FTA disagrees with the commenter who suggested that a potential conflict of interest would exist if a State drafted and certified a safety plan on behalf of a small transit provider. The funding relationships created by Congress differ from the new safety relationships in 49 U.S.C. 5329(d). From a federal perspective, the State has no role in safety enforcement or oversight of small Section 5307 providers. For rail transit agencies, the SSOAs serve in a different, independent role, and they are required by 49 U.S.C. 5329(e) to provide enforcement. Moreover, as a legal matter, the statutory provisions of 49 U.S.C. 5329(d) require States to draft and certify safety plans on behalf of small Section 5307 providers.

If a transit agency grows in size so that it no longer is considered "small," then it would have one year to draft and certify its own safety plan. The safety plan developed by the State would remain in effect until the transit agency drafts its own safety plan.

Finally, FTA does not agree that the rule text should be clarified to distinguish between a State's role and an SSOA's role in the development and certification of safety plans. The rule provides that a State must draft and certify safety plans only on behalf of small public transportation providers that do not operate rail service, and that an SSOA must review and approve a rail transit agency's safety plan.

3. Small Transit Providers May Draft and Certify Their Own Safety Plans

Comments: Many commenters asserted that, when a transit agency "opts out" of the state-wide safety plan and drafts and certifies its own plan, then the final rule should clarify that the State has no further obligation related to the safety plan.

One commenter observed that the "opt out" provision places the decision on a State's responsibilities in the hands

of its subrecipients instead of the State, which is where that responsibility exists in the context of funding relationships. The commenter recommended that FTA clarify in the final rule that the State is responsible for its own safety plan and for those of its subrecipients, and that the determination of whether the State will draft plans for its subrecipients remains at the discretion of the State.

Response: If a transit agency "opts out" and decides to draft and certify its own safety plan, then the State has no further responsibility regarding that safety plan and the transit agency may seek guidance and technical assistance directly from FTA. FTA disagrees with the commenter who suggested that States should have the discretion to draft and certify safety plans. In an effort to reduce the administrative and financial burdens of small public transportation providers, and given the statutory requirements of 49 U.S.C. 5329(d), FTA is requiring States to draft and certify safety plans on behalf of small Section 5307 recipients and subrecipients. FTA is providing those recipients and subrecipients with the discretion to "opt out" of this arrangement (however, the State will not have the option to "opt out," as this discretion lies with the small transit operator).

4. Direct and Designated Recipients Drafting and Certifying Safety Plans on Behalf of Smaller Transit Providers

Comments: Several commenters responded to FTA's question about whether a Section 5310 recipient should draft and certify their own safety plans if they are direct recipients, instead of having the States draft and certify their safety plans on their behalf. Many commenters stated that the designated or direct recipient should have this responsibility for themselves, given the fact that they do not receive their funds through the State under recent changes to the Section 5310 program under the FAST Act. One commenter supported the idea of having designated recipients draft and certify their own safety plans, as well as their subrecipients, only if the plans are based on templates provided by FTA. One commenter asked whether the State or the transit agency should be responsible for reviewing safety plans when a subrecipient receives funding through the transit agency and not the

Response: FTA appreciates the comments that it received regarding this issue. In light of the public comments that FTA received regarding the application of this rule to Section 5310 and Section 5311 recipients, FTA is deferring regulatory action regarding the

applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. Further evaluation of information and safety data related to these operators is needed to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators. At this time, the rule does not apply to an operator of a public transportation system that only receives Federal financial assistance under 49 U.S.C. 5310, 49 U.S.C. 5311, or both 49 U.S.C. 5310 and 49 U.S.C. 5311. Consequently, States are not required to draft and certify safety plans on behalf of operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds.

Consistent with the statutory provisions of 49 U.S.C. 5329(d)(3)(B), a State still has the responsibility of drafting and certifying safety plans on behalf of small Section 5307 recipients, unless they opt to draft and certify their own safety plans. To ease the burdens with these efforts, FTA is issuing a safety plan template with today's rule to assist States and smaller operators with the drafting and certification of their plans.

E. Existing System Safety Program Plan Is Effective for One Year

1. General Comments

Comments: A couple of commenters suggested that the final SSO rule and the proposed PTASP rule are contradictory in terms of implementation deadlines, and they recommended that FTA allow an SSPP to remain in effect until an SSOA has approved a rail transit agency's new PTASP. One of these commenters stated that FTA should remove all requirements involving SSPPs from the final PTASP rule. One commenter asked if a rail transit agency must keep its SSPP and reference it in its PTASP.

Response: FTA acknowledges that the compliance dates in the final SSO rule at 49 CFR part 674 differ from those in the PTASP rule at 49 CFR part 673. These compliance dates are creations of statute. Pursuant to 49 U.S.C. 5329(e)(3), each State must have an SSO program compliant with the new SSO rule within three years after the effective date of that final rule. Pursuant to 49 U.S.C. 5329(d)(1), each operator of a public transportation system must have a PTASP compliant with the new PTASP rule within one year after the effective date of this final rule.

Although these compliance dates differ, an SSOA can apply the regulatory requirements of the PTASP rule and

ultimately review and approve a PTASP based on those requirements, even if it has not fully developed its new program standard in accordance with the new SSO rule. As demonstrated through the SSPP-PTASP Crosswalk that FTA posted to this rulemaking docket, the substantive elements of the old SSPPs carry over into the SMS portions of PTASPs. The same basic requirements exist, albeit, reshuffled into a different format that is intended to more effectively address safety risks. Finally, the staff of SSOAs have been taking training courses in SMS in accordance with the interim rule for the Public Transportation Safety Certification Training Program. Given the above, FTA expects each SSOA to review and approve each PTASP of a rail transit agency within its jurisdiction, even if it has not fully complied with the new SSO rule at 49 CFR part 674.

Ultimately, the SSPP will become obsolete one year after the effective date of this final rule, and an agency's PTASP will replace the SSPP. However, if a transit agency would like to maintain the SSPP and use it as a reference document, it may do so. FTA only will conduct oversight, including Triennial and State Management Reviews, to ensure that a transit agency's PTASP complies with this rule, not its former SSPP. Given the April 15, 2019 deadline for updated SSO Programs under 49 CFR 674.11, FTA believes that the effective date and compliance date of today's final rule will provide rail transit agencies and their SSOAs with more time to harmonize their safety plans and program standards before they are finalized.

2. One-Year Compliance Timeframe

Comments: Several commenters provided input on the one-year compliance timeframe for the proposed rule. One commenter expressed support for the one-year compliance period, but stated that transit agencies may need more than one year to draft their safety plans, hire and train the necessary personnel, and certify the plan.

Some commenters stated that FTA should provide a longer compliance/implementation period for the rule. Several of these commenters remarked that the proposed compliance period is aggressive and may lead to rushed or subpar safety plans with limited SMS training for staff. The commenters also suggested that a longer compliance period may be necessary given the requirements for a signature from the Accountable Executive and approval from a Board of Directors. One commenter suggested that,

notwithstanding Federal requirements, State legislatures may not be able to amend State safety requirements prior to the compliance deadline for this rule, which may force some transit agencies to create two safety plans for purposes of Federal and State law, or be in noncompliance with the Federal and State laws.

Most commenters provided suggestions for an alternative compliance deadline, with many commenters suggesting that FTA extend the compliance deadline to two years. Several commenters suggested that FTA extend the compliance deadline or allow for a multi-part implementation or a transitional grace period for agencies to show progress with the development of their safety plans. A couple of commenters recommended that FTA extend the compliance period until one year after FTA issues templates for safety plans. One commenter stated that the compliance deadline for this rule should be tied to the finalization of the National Public Transportation Safety Plan. Several commenters also suggested aligning the compliance deadline of this rule with the two-year compliance deadline for the Transit Asset Management rule.

Response: As a preliminary matter, FTA notes that many commenters referred to the "implementation" deadline of this final rule, as opposed to the rule's "compliance" deadline. The compliance deadline is the date by which transit operators and States must comply with the final rule and have a safety plan in place. FTA emphasizes that this rule implements a statutory requirement that each operator of a public transportation system draft and certify a safety plan within one year after the effective date of this final rule. The safety plan must include all of the information, processes, and procedures as outlined in this rule. FTA expects each operator of a public transportation system to "implement" the processes and procedures outlined in its safety plan after it drafts and certifies that plan in accordance with this rule. That implementation should take place continually, and the implementation, particularly the implementation of SMS, should mature over time. But to comply with this rule, each operator of a public transportation system must draft and certify a safety plan within one year after the effective date of this final rule—that one-year deadline is the 'compliance'' deadline for this rule.

The one-year compliance deadline was created by the statutory provisions of 49 U.S.C. 5329(d)(1), and FTA does not have the flexibility to extend it. Nevertheless, FTA does not expect that

all transit agencies will have fully implemented SMS one year after the effective date, but rather, FTA expects that transit agencies will have the processes and procedures put in place for SMS, including hazard identification, risk analysis, and the Safety Assurance procedures as outlined in Subpart C of this rule. The full implementation of SMS may take longer, in some cases years to fully mature in large multi-modal transit agencies. FTA is providing more guidance on how a transit agency may fully implement a mature SMS in the National Public Transportation Safety Plan, and it intends to provide additional guidance and technical assistance to the industry in the future.

FTA appreciates the comments that it received suggesting that transit agencies may need more than one year to certify compliance with the rule. Although, by statute, the compliance deadline must be one year from the rule's effective date, FTA has discretion on setting the effective date itself. In response to the public comments and in an effort to assist the industry with meeting the requirements of this rule, FTA is making the effective date one year after its publication date. As a result, transit agencies will have a total of two years (one year from the publication date to the effective date, plus another year from the effective date to the compliance deadline) to certify that they have safety plans meeting the requirements of 49 CFR part 673.

F. Certification of Safety Plans

Comments: Several commenters requested additional information on how agencies may certify compliance with this rule and what this certification means. One commenter remarked that the rule contains neither a definition nor an explanation of the term "certification" or "certify." Two commenters questioned how an agency may certify their safety plans if FTA may adopt additional performance measures in the future.

One commenter expressed concern with self-certification, asserting that self-certification is not a reliable method for establishing effective safety management by public transportation providers. This commenter suggested that each transit agency should submit its safety plan to FTA for approval and certification so that FTA could verify that the plan satisfies the statutory and regulatory requirements.

Several commenters expressed concern over the one-year certification timeline, indicating that one year may not be enough time for transit agencies to certify compliance with the rule. One commenter suggested that FTA lengthen the certification period to two years, which would provide agencies with additional time and align the certification deadline for the compliance deadline for developing transit asset management plans as outlined in the TAM rule.

One commenter urged FTA to clarify the process by which a State should certify a safety plan on behalf of a Section 5310, Section 5311, or small Section 5307 recipient or sub-recipient. Additionally, the commenter asked who would conduct oversight on a safety plan if a small transit agency opts out of any plan developed by a State.

Response: As a statutory matter, pursuant to 49 U.S.C. 5329(d)(1), each recipient or State must "certify" that the recipient or State has established a comprehensive agency safety plan. Pursuant to 49 U.S.C. 5323(n), each recipient must submit to FTA a list of "Certifications and Assurances" as part of the grant award and oversight process during each fiscal year. FTA will use this existing Certifications and Assurances process to satisfy the statutory requirement for safety plan certifications. FTA has added a section to the list of Certifications and Assurances to address safety. FTA will issue future guidance on how States can certify safety plans and transit asset management plans on behalf of transit operators.

To the extent that FTA amends the National Public Transportation Safety Plan in the future, or any of its regulatory requirements in general, FTA will amend the annual list of Certifications and Assurances, as necessary.

FTA appreciates concerns regarding the self-certification process; however, FTA does not have the resources to collect and review hundreds of safety plans each fiscal year. Consequently, FTA intends to utilize its existing risk-based approach to oversight by using its Triennial Reviews and State Management Reviews to ensure compliance with this rule. FTA notes that it does not need to wait to review a safety plan every three years. FTA may review an agency's safety plan whenever it deems necessary.

As noted above, in response to the public comments and in an effort to assist the industry with meeting the requirements of this rule, FTA is making the effective date one year after its publication date. As a result, transit agencies will have a total of two years from the rule's publication date to certify that they have safety plans meeting the requirements of 49 CFR part 673.

G. SSOA Review and Approval of PTASPs for Rail Transit Systems

Comments: Pursuant to the proposed provisions at 49 CFR 673.13(a), each SSOA would be required to review and approve a PTASP developed by a rail fixed guideway system. Some commenters expressed concern with the one-year deadline that a transit agency has to certify its PTASP and the threeyear deadline that an SSOA has to comply with the new SSO rule at 49 CFR part 674. One commenter recommended that FTA should allow rail transit agencies to certify compliance with the PTASP rule one year after the relevant SSOA develops its program standard pursuant to 49 CFR part 674. Several commenters questioned whether a rail transit agency must submit its PTASP to the SSOA by one year after the PTASP final rule's effective date, or whether the SSOA must approve the agency's PTASP by one year after the PTASP rule's effective date. Several commenters urged FTA to clarify whether SSOAs must update their program standards prior to approving rail transit safety plans since most SSOAs will be operating under a program standard based on 49 CFR part 659 when the PTASP final rule becomes

A few commenters requested FTA to clarify the role of an SSOA with respect to PTASP certification. One commenter suggested that a PTASP should not be executed without SSOA approval. Several commenters suggested that FTA develop guidance for obtaining SSOA approval and a resolution process for situations in which a rail transit agency certifies compliance and then an SSOA does not approve the safety plan. Several commenters requested clarification of an SSOA's approval power and role, with a couple of these commenters encouraging FTA to modify the rule's text to make clear that SSOAs only have authority over rail transit systems. One commenter recommended that FTA require transit agencies that operate rail and bus service to develop separate safety plans for rail and bus service so that it is easier for SSOAs to approve the plans for rail safety.

A few commenters stated that FTA should define the SSOA's role and responsibilities in approving plans that contain modes of service not subject to state specific oversight rules, such as rules for bus transit. The commenters argued that while SSOAs are responsible for the review and approval of rail transit plans, FTA's proposed rule only specifies that bus agencies will self-certify.

Several commenters expressed concerns over the requirement to have the transit agency's Board of Directors and the SSOA approve the safety plan, fearing that this two-tiered review process could subject plans to conflicting evaluation criteria, which could weaken plans and cause delays in implementation.

One commenter suggested that FTA should clarify that SSPPs will become obsolete.

Response: As a preliminary matter, FTA notes that the comments above regarding state safety oversight are more appropriately addressed through FTA's SSO rule at 49 CFR part 674, which governs the activities of SSOAs. FTA's PTASP rule governs the activities of operators of public transportation systems. Nevertheless, to provide the industry with additional clarification regarding the role of SSOAs, FTA provides the responses below.

Through FTA's new SSO rule at 49 CFR part 674, each SSOA has a great deal of flexibility regarding the timing of its approval of a PTASP within its jurisdiction. Pursuant to the new rule, each SSOA is obliged to "adopt and distribute a written SSO program standard" consistent with the National Public Transportation Safety Plan and the PTASP rule (49 CFR 674.27(a)); "explain" an SSOA's "role . . . in overseeing" a rail transit agency's "execution of its Public Transportation Agency Safety Plan" (49 CFR 674.27(a)(4)); and "describe the process whereby the SSOA will receive and evaluate all material submitted under the signature of [a rail transit agency's] accountable executive" (49 CFR 674.27(a)(4)). Given these requirements, an SSOA could choose to "approve" a PTASP at virtually any point in time, and as often as it might like. FTA expects each SSOA to develop its program standard in consultation with the rail transit agencies within the SSOA's jurisdiction. FTA intends to provide deference to the State decision makers on this matter.

Optimally, an SSOA would have its program standard in place before reviewing the merits of a rail transit agency's PTASP, but it is not necessary, as a matter of law. An SSOA still operating under the old SSO rule at 49 CFR part 659 and transitioning to the new SSO rule at 49 CFR part 674 still can judge the adequacy of a rail transit agency's PTASP by applying the standards and regulatory requirements set forth in the new rules at 49 CFR parts 673 and 674.

Through the new SSO rule, FTA addresses scenarios in which an SSOA does not approve a PTASP. Pursuant to

49 CFR 674.29(c), "In an instance in which an SSOA does not approve a Public Transportation Agency Safety Plan, the SSOA must provide a written explanation, and allow the [rail transit agency] an opportunity to modify and resubmit its . . . Plan for the SSOA's approval." This mechanism should lead to negotiations that resolve disagreements between an SSOA and a rail transit agency. In those instances in which an SSOA and a rail transit agency continue to disagree in good faith, FTA may step into the dispute to help the issue. If a rail transit agency is comfortable certifying its own compliance with the rules, but it receives objections or disapprovals from its SSOA, then FTA could take regulatory enforcement action under the Public Transportation Safety Program rule at 49 CFR part 670 (see https:// www.gpo.gov/fdsys/pkg/FR-2016-08-11/ pdf/2016-18920.pdf), as necessary and appropriate, to ensure compliance with the PTASP rule.

It is abundantly clear in 49 U.S.C. 5329(e) and FTA's new SSO rule at 49 CFR part 674 that an SSOA only has jurisdiction over a "rail fixed guideway public transportation system" that is not subject to regulation by FRA. Consequently, when reviewing a PTASP for an agency that operates rail fixed guideway public transportation and bus public transportation, an SSOA should focus its review on the rail fixed guideway public transportation system only, given the fact that as a legal matter, Federal law does not give an SSOA the authority to regulate the safety of bus systems. Unless provided by State law, an SSOA has no legal authority to compel a transit agency to change its safety practices for bus operations. FTA disagrees with the commenters who believe that FTA should require separate safety plans for rail and bus; FTA will defer to each transit agency to decide whether it is more appropriate for their system to have a single plan covering rail and bus (and other modes of transit) or whether to have multiple plans for each mode of transit.

Finally, FTA re-emphasizes that every operator of a public transportation system subject to this rule, or State, must certify compliance with this rule, whether it provides rail transit service, bus transit service, or other modes of transit service. SSPPs will become obsolete one year after the effective date of this final rule.

H. Safety Performance Targets and Performance-Based Planning

Comments: Pursuant to the proposed provisions at 49 CFR 673.15, each

transit agency or State would be required to make its safety performance targets available to States and MPOs to aid in the planning process, and each transit agency or State would be required to coordinate with States and MPOs in the selection of safety performance targets.

Several commenters generally supported the coordination provisions. One commenter supported flexibility in the target-setting process and coordination of targets between the State, regional, and transit agency levels. One commenter was encouraged that FTA acknowledged the vital role of the planning process in safety management and recommended that the Transit Asset Management Plans also be included in the coordination process.

A couple of commenters asked FTA to explain the purpose of communicating safety performance targets to States and MPOs. One commenter asked FTA to clarify the MPO's role in the planning process, stating that if an MPO has any approval or review authority of safety performance targets, then an MPO should be required to have the same safety expertise and training as an SSOA.

Several commenters asked whether a transit agency only would be required to make its targets available to a State and an MPO, or whether it also would be required to make the supporting performance data pertaining to those targets available to a State and an MPO. One commenter suggested that FTA avoid creating this requirement or to make a general requirement that transit agencies cooperate with States and MPOs in the planning process.

Several commenters expressed concerns with requiring coordination among planning organizations. They argued that this coordination would be unreasonably burdensome on some transit agencies. Several commenters argued that these provisions are not required by statute and that MPOs generally do not operate transit service and do not have transit operations and safety expertise or experience. Several commenters suggested that coordination should be revised to a "consultation" requirement. One commenter recommended that FTA delete these requirements, and that planning coordination should be encouraged through guidance instead.

Several commenters requested clarification on how a State or transit agency should coordinate with MPOs and States to select safety performance targets. One of these commenters argued that if by "coordination," FTA's intent is that a transit agency share its PTASP (which will include performance

targets) with States and MPOs, then FTA should clearly state such a requirement. Additionally, the commenter stated that the proposed rule did not specify which State agencies, other than MPOs, transit agencies are expected to coordinate with.

Several commenters asked which accountability measures will be used to ensure that coordination is occurring "to the maximum extent practicable." One commenter asked what recourse an MPO would have if the State or transit operator chooses not to coordinate on target setting, claiming there is not a "practicable" way to do so. The commenter argued that the rule must recognize that target setting across multiple functions and dimensions would require an extremely robust degree of coordination and suggested removing that phrase.

One commenter stated that the proposed rule does not identify the responsibilities of the State in the planning process. Another commenter asked whether States and MPOs would be required to keep confidential any information related to safety performance targets.

One commenter stated that it is unclear how the development of performance targets at the State and MPO levels will impact individual transit agency targets in the future, particularly when FTA may develop safety performance targets under a separate NPRM. This commenter also said it is unclear how the State and MPO safety performance targets would impact individual transit agency safety plans, as these are to be determined at the local level by each individual transit agency.

Response: FTA appreciates the comments that it received in support of its proposed safety performance target provisions. FTA emphasizes that these requirements are rooted in the statutory provisions of 49 U.S.C. 5329(d)(1)(E), which requires each operator of a public transportation system subject to this rule to include in its PTASP "performance targets based on [FTA's] safety performance criteria and state of good repair standards." Moreover, the statutory provisions of 49 U.S.C. 5303(h)(2)(B) and 49 U.S.C. 5304(d)(2)(B) further require that "[s]election of performance targets by a metropolitan planning organization shall be coordinated, to the maximum extent practicable, with providers of public transportation to ensure consistency with sections . . . 5329(d)" and "[s]election of performance targets by a State shall be coordinated with the relevant metropolitan planning organizations to ensure consistency to

the maximum extent practicable." Since these activities are required by law, FTA will not merely encourage these practices through guidance, as some commenters requested. FTA will require these practices as a legal matter. Moreover, FTA emphasizes that the PTASP rule only governs the activities of operators of public transportation systems. The recent FTA/FHWA joint planning rule 23 CFR part 450 governs the planning activities of transit agencies, States, and MPOs. FTA refers readers to the Final Rule dated May 27, 2016, for further guidance on the roles and responsibilities of States and MPOs in the planning process (see https:// www.gpo.gov/fdsys/pkg/FR-2016-05-27/ pdf/2016-11964.pdf).

In response to the question as to whether a transit agency only would be required to make its safety performance targets available to a State and an MPO, or whether it also would be required to make the supporting performance data pertaining to those targets available to a State and an MPO, FTA defers to the State and local processes developed by States and MPOs. FTA only requires that transit agencies coordinate with States and MPOs to the maximum extent practicable to assist those States and MPOs with the selection of Statewide and regional safety performance targets. At a minimum, FTA requires each operator of a public transportation agency to make its safety performance targets available to States

To ensure that a transit agency complies with these requirements, FTA intends to utilize its existing Triennial Reviews and State Management Reviews. FTA intends to ensure that MPOs comply with the joint planning rule through the existing MPO certification process.

and MPOs.

Finally, FTA notes that it is not developing safety performance targets for the industry—it is developing safety performance measures by which each operator of a public transportation system, and each State and MPO, must set targets. These targets are intended to guide transit agencies, States, and MPOs with the prioritization of transportation investments. The goal is for the prioritization of capital investments that help meet safety performance targets and state of good repair targets.

- I. Safety Management Systems
- 1. Safety Management Policy: General Comments

Comments: Numerous commenters expressed general support for the proposed Safety Management Policy provisions of 49 CFR 673.23.

Response: FTA appreciates the support from the transit industry on Safety Management Systems, and specifically the Safety Management Policy provisions of 49 CFR 673.23.

1.1. Safety Management Policy Statement

Comments: Several commenters encouraged FTA to allow for maximum flexibility in safety management policy statements and urged FTA to allow deviation in policy adoption whenever consistent with the overarching principles of SMS.

A few commenters expressed concern regarding the inclusion of safety performance targets in the safety management policy statement. One commenter suggested that it is inappropriate to include specific safety performance targets in an overarching safety management policy statement and suggested deleting the requirement from the rule. This commenter also suggested that FTA replace the term SMS with PTASP where references to safety performance targets are made. Another commenter urged FTA to clarify that the intent of including safety performance targets in the safety management policy statement is not to require annual updates of the target values, but rather, the measures that the targets address.

Response: FTA agrees with the commenters who suggested that the inclusion of safety performance targets in the safety management policy statement is unnecessary, and FTA has updated the rule text, accordingly. The location of this requirement under the "Safety Management Policy" section of this rule is redundant, given the fact that FTA is requiring each transit agency to establish safety performance targets through the "General Requirements" section of this rule at 49 CFR 673.11(a)(3). If a transit agency wishes to include its safety performance targets in its safety management policy, it may do so, although it may identify those targets in another section of its safety plan. The rule text in 49 CFR 673.23 now reads, "A transit agency must establish its organizational accountabilities and responsibilities and have a written statement of safety management policy that includes the agency's safety objectives."

To clarify, during a transit agency's annual review and update of its safety plan (which is required under 49 CFR 673.11(a)(5)), a transit agency may need to update its safety performance targets based on the data and safety conditions at that time, but a transit agency may not necessarily need to alter its target values each year. A transit agency only

needs to examine them and decide, for itself, whether it should amend them.

1.2. Employee Reporting Program

Comments: Numerous commenters expressed support for FTA's proposed employee reporting program. Several commenters urged FTA to provide more detail on the requirements for employee reporting programs. Two commenters suggested that FTA encourage transit agencies to establish "close call" reporting programs. Another commenter requested guidance from FTA on how reports from employee reporting programs would be protected from disclosure.

One commenter supported nonpunitive employee reporting, but stated that disciplinary actions for employee safety behaviors are the subject of collective bargaining at the majority of transit systems. As such, the commenter stated that collective bargaining agreements may affect disciplinary actions in employee reporting programs.

Response: FTA appreciates the support for employee reporting programs and believes it is an essential part of a transit agency's SMS. Pursuant to 49 CFR 673.23(b), FTA is requiring each transit agency to "establish a process that allows employees to report safety conditions to senior management," and FTA is providing significant latitude and flexibility to transit agencies to determine their own processes for the reporting of safety conditions. These reporting processes could include hotlines, web-based reporting systems, form-based reporting systems, or direct reporting to management, but ultimately, each transit agency must decide the process and procedures that will work best within that individual agency.

"Close call" reporting systems are a type of employee reporting, and FTA strongly supports the establishment of close call reporting systems, although these systems are not required.

Currently, FTA does not have statutory protections in place to protect safety information from public disclosure, as is the case with FRA and the System Safety Programs required of commuter and intercity passenger railroads under 49 CFR part 270 (see http://www.fra.dot.gov/eLib/Details/ L18294). FTA requested these protections through the "Grow America Act". Following this request, in Section 3021 of the FAST Act, Congress authorized a study "on evidentiary protection for public transportation safety program information." The results of this study will help inform the need to develop statutory and regulatory protections for safety data.

Finally, FTA acknowledges that disciplinary actions for employee safety behaviors may be the subject of collective bargaining agreements throughout the country. Consequently, many transit agencies may need to work with their labor unions to establish employee safety reporting programs that fit the needs of management and a transit agency's operational and maintenance staff.

1.3. Safety Accountabilities and Responsibilities

Comments: Two commenters expressed concern over the requirement that each transit agency employ an Accountable Executive and either a Chief Safety Officer or an SMS Executive. These commenters argued that this requirement could be overly burdensome for rural, specialized, tribal, or small transit systems where the administrative staff could be limited to only a single executive. One commenter suggested that FTA add language in the final rule that requires small transit agencies to hire necessary safety personnel. Another commenter urged FTA to clarify whether the Chief Safety Officer must be a direct employee of the transit agency or whether the Chief Safety Officer may be a position held by a part-time employee.

A few commenters provided input on the role of the Chief Safety Officer and other SMS executives. One commenter urged FTA to clarify the role of the Accountable Executive in relation to the Chief Safety Officer and the transit agency's Chief Executive Officer. The commenter argued that the proposed rule would require the Accountable Executive to implement and maintain SMS, but that responsibility should belong to the Chief Safety Officer. One commenter suggested that FTA identify the link between the transit agency's Chief Safety Officer or SMS Executive and the operations and asset management departments, which is integral for a successful SMS.

Response: FTA appreciates the comments that it received regarding the Accountable Executive and the Chief Safety Officer (or SMS Executive), however, FTA is requiring that each transit agency identify individuals to fill these positions in its system. FTA clarified in the NPRM for this rule, and it is clarifying again here, that at many smaller transit agencies, roles and responsibilities may be more fluid and shared. Nevertheless, even in circumstances where responsibilities are either shared or delegated, each transit agency must identify a single primary decision-maker, or "Accountable Executive," who is ultimately

responsible for controlling the human and financial resources necessary to maintain and implement the transit agency's safety plan and transit asset management plan.

FTA acknowledges that small transit agencies may not have many executive staff, and therefore, FTA is allowing small Section 5307 recipients and subrecipients to identify a Chief Safety Officer, or "SMS Executive," that may serve other functions, such as operations, maintenance, and grant administration. For these transit agencies, the Chief Safety Officer may be a full-time employee of the transit system who has responsibility for duties other than safety, a part-time employee of the transit system, or a contracted employee. To illustrate, in a small bus agency, the general manager or operations manager may be the same individual as the Chief Safety Officer or SMS Executive.

Given the increased safety risks and complex operations associated with rail transit systems, FTA is requiring each rail transit agency to identify a single full-time Chief Safety Officer solely dedicated to safety. These Chief Safety Officers cannot have responsibilities other than safety. Similarly, FTA expects bus transit systems that operate more than 100 vehicles in peak revenue service to have a dedicated Chief Safety Officer, given the increased safety risks in those systems, although, this is not a requirement.

The role of the Accountable Executive in relation to the Chief Safety Officer and transit agency's CEO may vary from system to system. In many cases, as a transit agency's CEO or president or general manager, that individual likely will serve as the Accountable Executive. The Accountable Executive and the Chief Safety Officer are responsible for implementing and maintaining a transit agency's SMS, although at smaller transit agencies, this individual may be the same person. Ultimately, as noted above, the Accountable Executive must be the individual with the authority to dedicate the human and financial resources to maintain and implement a transit agency's safety plan and transit asset management plan. The Accountable Executive should oversee, and the Chief Safety Officer should have a strong working relationship with, the operations and asset management departments at a transit agency in order for SMS to be successful and effective.

2. Safety Risk Management

2.1. Safety Risk Management: General Comments

Comments: Two commenters supported the general inclusion of a safety risk management process in a safety plan as detailed in the NPRM, but expressed concern about the level of data collection and assessment activities required. The commenters recommended that FTA provide best practices and technical assistance to assist States and transit agencies with the preparation and execution of safety risk management processes. Similarly, a commenter expressed concerns over the data requirements of the proposed rule, noting that the commenter's organization employs hazard identification and tracking logs, but the organization now would have to incorporate into its SMS the data obtained through these systems. The commenter asked FTA to clarify if it would need to apply a safety risk management process for paratransit services, and this commenter asked where transit asset management fits into the safety risk management process.

While stating that safety risk management is an essential component of SMS, a commenter asserted that the proposed provisions at 49 CFR 673.25 do not specify that hazard analysis, risk assessment, or safety certification is required for new and major capital projects. Additionally, the commenter suggested that the rule fails to address configuration management or risk assessments to system alterations, and it does not require transit agencies to consider the results of asset condition assessments while performing safety hazard identification activities. This commenter also asserted that the proposed rule suggests, but would not require, that the results of asset condition assessments and SMS analysis be considered in the determination of whether an asset meets the SGR standards under FTA's Transit Asset Management rule at 49 CFR part 625.

One commenter asked what the phrases "new operations of service to the public" and "new operations or maintenance procedures" mean, as used in the section-by-section analysis of the proposed 49 CFR 673.25(a). Additionally, the commenter stated that the definition of safety risk management is unclear.

Two commenters encouraged FTA to allow flexibility in the hazard identification and risk management processes. One of these commenters stated that transit agencies should be encouraged to incorporate existing

hazard identification and risk management processes, and evaluate any new processes that may be more effective. The other commenter asked whether a transit agency must develop its own safety risk management process, or whether FTA will establish a nationwide model.

One commenter remarked that there are organizational pressures exerted on the safety staff and other personnel who participate in the safety risk management process to rate safety risk as low as possible. This commenter expressed a hope that with the full implementation of SMS in an organization, these types of organizational pressures would dissipate under a positive safety culture, but cautioned that the development of a positive safety culture could take five to six years, or even longer, in many organizations.

Response: FTA appreciates the support from the industry on the proposed safety risk management process. FTA intends this process to be flexible, and it avoided prescriptive requirements in this rule. For example, the level of data collection and assessment activities will vary from agency to agency. For some transit agencies, data collection and analysis processes could be conducted using computer software programs; at other transit agencies, especially at smaller transit agencies, the data collection and analysis processes could involve a transit agency's management team, staff, and bus operators meeting in a room and discussing the most significant safety hazards and evaluating any associated risks. FTA has produced a safety plan template with this final rule, and it should assist transit agencies with the development of Safety Risk Management processes and considerations. To be clear, this rule applies to any transit service not regulated by another Federal agency, including general public and ADA complementary paratransit service, so each transit service provider will need to develop a safety plan which includes a Safety Risk Management process.

Also, each transit agency must apply its Safety Risk Management processes—and all other SMS processes—to all elements of its operations, including the design, construction, and operation of major capital projects, New Starts and Small Starts projects, and any other extension or expansion of transit service. These requirements extend to any "new operations or maintenance procedures," meaning, any new operations or maintenance processes for railcars, buses, track, facilities, or other service or infrastructure undertaken by

a transit agency. FTA is providing a great deal of flexibility here and is allowing systems to determine the hazards and risks for which it will prioritize and mitigate from an individual agency level. A transit agency also must apply its Safety Risk Management process to its existing operations and maintenance procedures, and all other aspects of its system. Pursuant to 49 CFR 673.5, FTA is defining the term "Safety Risk Management" to mean "a process within a transit agency's Public Transportation Agency Safety Plan for identifying hazards and analyzing, assessing, and mitigating safety risk." FTA outlines the scope of necessary procedures within Safety Risk Management 49 CFR 673.25.

With respect to condition assessments, FTA expects each transit agency to consider the results of its condition assessments undertaken pursuant to its Transit Asset Management plan when it conducts SMS activities. For example, if an asset does not meet a transit agency's state of good repair targets, then the transit agency may conduct Safety Risk Management activities and analysis to determine whether the asset presents a safety hazard and any safety risks. The transit agency could mitigate any risks and prioritize investments in its capital plan, accordingly. In an effort to provide flexibility and scalability, FTA defers to each transit agency to determine for itself its own processes and procedures for these activities.

FTA agrees with commenters who suggested that transit agencies should be encouraged to incorporate existing hazard identification and risk management processes, and utilize any new processes that may provide a more effective means of identifying and addressing safety hazards and safety risks. FTA is providing a safety plan template, technical assistance, and guidance to assist transit agencies with the development and implementation of Safety Risk Management, and it is not applying a one-size-fits-all model for the industry since safety hazards and safety risks vary significantly nationwide.

One of the goals of this rule is create stronger and more positive safety cultures within transit agencies, and FTA expects that a transit agency's personnel would not feel pressure to rate all safety risks as low as possible. To the extent this sentiment exists within a transit agency, FTA anticipates that these types of practices would dissipate as a transit agency implements its SMS over time. FTA agrees that it may take a few months to even a few years to fully implement a mature SMS,

and FTA will provide guidance and technical assistance to the industry, as necessary.

2.2. Safety Hazard Identification and Analysis

Comments: One commenter suggested that FTA clarify the distinction between safety hazard analysis and safety risk evaluation. This commenter asserted that FTA should articulate this distinction because the concepts of evaluation and analysis are used interchangeably in common language. Another commenter asked FTA to define the term "consequence."

A commenter encouraged FTA to establish standard processes for hazard identification and provided FTA with the hazard analytical methods and safety risk determination techniques adapted from the U.S. Department of Defense's Military Standard 882 series of standards as a model for national standardization. Similarly, one commenter suggested that FTA specify that transit agencies must utilize data and information from oversight authorities, including FTA, when conducting hazard identification and risk analysis.

Response: In an effort to provide clarity to the Safety Risk Management process, FTA has amended the terminology used in the final rule. A transit agency must develop a Safety Risk Management process that is comprised of three steps: (1) Safety hazard identification, (2) safety risk assessment, and (3) safety risk mitigation. A transit agency must first identify potential hazards throughout its system, and then it must analyze these hazards to determine whether they present safety risks and safety consequences. After a transit agency identifies and analyzes potential hazards and consequences, the agency must undertake activities to assess and prioritize the safety risk associated with the potential consequences of the identified safety hazards, in accordance with 49 CFR 673.25(c). This process includes an evaluation wherein the transit agency assigns a level of probability and severity to the consequences, and then develops mitigation, as necessary and appropriate. FTA encourages transit agencies to utilize computer software programs for safety risk assessment and mitigation, although smaller transit operators may not need them.

FTA has taken efforts to avoid requiring prescriptive processes for hazard identification and risk analysis. FTA encourages transit agencies to review the U.S. Department of Defense's Military Standard 882 (available at

http://www.system-safety.org/ Documents/MIL-STD-882E.pdf) and utilize the hazard analytical methods and safety risk determination techniques, to the extent appropriate, but FTA is not mandating that transit agencies adopt any particular method of process for hazard identification and risk analysis—FTA is providing transit agencies with flexibility given the large range of sizes and types of operators nationwide. Finally, FTA will not specify the type of data and information that oversight authorities must share with transit agencies. Oversight authorities and transit agencies will need to make these decisions for themselves.

3. Safety Assurance

3.1. Safety Assurance: Safety Performance Monitoring and Measurement

Comments: Pursuant to the proposed provisions at 49 CFR 673.27(b)(2), each operator of a public transportation system would be required to monitor its operations to identify any potential safety hazards not previously identified through the Safety Risk Management process outlined in proposed 49 CFR 673.27. One commenter suggested that FTA delete this requirement because, presumably, transit agencies already would have established activities to identify potential safety hazards as part of their Safety Risk Management processes. One commenter suggested deleting the word "any" in the requirement because the word suggests that safety risk mitigations may not exist and/or the transit agency's Safety Risk Management Process is broken. One commenter asked what type of hazards might not be identified in the Safety Risk Management process and asked whether the proposed requirement indicates a flaw in the Safety Risk Management process.

A couple of commenters requested clarification of the term "safety event" as used in proposed 49 CFR 673.27(b)(4). Specifically, a transit agency asked if a "safety event" in this provision is the same as "Event" as defined in the proposed rule. If the terms are the same, then the commenter asked whether a transit agency would have to develop a process for investigating "Accidents," "Incidents," and "Occurrences." Additionally, the commenter asked to whom it should report a "safety event," if anyone.

Two commenters asserted that this aspect of SMS appears one-size-fits-all, perhaps appropriate for a large agency operating a rail system but burdensome for small-urban, rural, specialized, and

tribal transit agencies. Several commenters recommended that FTA should establish minimal monitoring requirements for Section 5310, Section 5311, and small Section 5307 recipients. These requirements should be scalable and reflect the size and scope of these organizations.

Response: FTA appreciates the comments that it received regarding the Safety Assurance processes proposed in the NPRM. FTA agrees with the commenter who suggested that the requirement for transit agencies to continually monitor their operations to identify any potential safety hazards that it might not have captured when undertaking its Safety Risk Management process is a redundant requirement. FTA has eliminated this requirement for all transit operators in the final rule.

Under the proposed provisions for Safety Assurance at 49 CFR 673.27(b)(4), a transit agency would be required to establish a process to: "Investigate safety events to identify causal factors." FTA proposed the following definition for the word, "event," as used throughout the rule: "Accident, Incident, or Occurrence." Therefore, each transit agency must develop procedures for investigating Accidents, Incidents, and Occurrences.

As discussed throughout this rulemaking, SMS is scalable, and FTA is providing transit agencies with great latitude and flexibility in developing procedures for investigating Events. For example, a small bus operator may develop a simple process for investigating the cause of a bus accident. The process may involve an on-site examination of the vehicle and the scene, a review of any video recordings from cameras mounted inside or outside of the bus, an interview with the bus operator and witnesses at the scene, and a toxicology test for the bus operator. A large rail operator may need to develop a more robust process for investigating the cause of a rail car accident, involving communications between safety and operating divisions of the transit agency, a shutdown of track operations, the deployment of designated safety inspectors and engineers, a comprehensive investigative report, etc. FTA is not prescribing any particular process for investigating safety events, but it notes that, as part of the larger safety management process, it is critical for transit agencies to identify and understand the causes of the Accidents, Incidents, and Occurrences in their systems so that the circumstances leading to the Events can be mitigated and prevented in the future.

FTA notes that its reporting requirements for safety events are outlined in the National Transit Database Reporting Manuals (see https://www.transit.dot.gov/ntd). Rail transit agencies should follow the notification and reporting requirements of the new SSO rule at 49 CFR part 674, including Appendix A to that rule. FTA is not requiring any reporting through this PTASP rule.

Finally, FTA agrees with the commenters who recommended that FTA should establish minimal monitoring requirements for smaller transit operators. Consequently, in today's final rule, FTA has eliminated many of the Safety Assurance requirements for all small public transportation providers. Small public transportation providers only would need to develop procedures for safety performance monitoring and measurement; they would not need to develop procedures for management of change and continuous improvement. FTA believes that these revisions reduce the administrative, financial, and regulatory burdens for small transit providers significantly and help them transition to the new part 673. Rail fixed guideway public transportation systems, and FTA recipients and subrecipients that operate more than 100 vehicles in peak revenue service, would be required to develop safety plans that include all of the processes under Safety Assurance, namely, safety performance monitoring and measurement, management of change, and continuous improvement.

3.2. Safety Assurance: Management of Change

Comments: One commenter emphasized the importance of the proposed provisions at 49 CFR 673.27(c) involving the management of change and assessing changes that may introduce new hazards or impact a transit agency's safety performance. This commenter suggested moving these requirements from the Safety Assurance provisions of the rule to the Safety Risk Management provisions of the rule, indicating that this relocation would elevate the importance of the requirement. One commenter requested clarification regarding which changes might impact a transit agency's safety performance.

Another commenter encouraged FTA to include Management of Change within the SMS context, stating that safety within the scope of capital projects, acquisitions, procurements, and system changes only fully can be measured and verified through system safety engineering practices and

principles. This commenter argued that Management of Change within the context of SMS should include effective safety management procedures and processes to ensure that plans, policies, procedures, and practices effectively are measured and incorporated into an overall Management of Change program. One commenter expressed confusion over the provision for transit agencies to map updates of their safety plans to Safety Assurance instead of Safety Management Policy.

Response: The Safety Assurance element of SMS involves the continual monitoring of a transit agency's safety performance. Safety Assurance activities serve as a check on the Safety Risk Management of a transit agency. The procedures are designed to ensure that safety risk mitigations are effective, to collect safety performance data that will help a transit agency predict future safety events and mitigate or eliminate them, and to analyze the potential safety risks of any new practices or procedures adopted by a transit agency. For these reasons, the "Management of Change" activities are housed within Safety Assurance. Each transit agency must establish a process for identifying and assessing changes that may introduce new hazards or impact the transit agency's safety performance, and if the transit agency determines that a change may impact its safety performance, then the transit agency must evaluate the proposed change through its Safety Risk Management process. FTA disagrees with the commenter who suggested that moving these procedures from Safety Assurance to Safety Risk Management will elevate their importanceultimately, these all are requirements for safety plans. FTA is providing each transit agency with great latitude and flexibility in developing these procedures and identifying the types of changes in its system that could impact safety performance. These changes may include changes to the design of a new public transportation system, service changes to the existing public transportation system, new operational or maintenance procedures, new organizational changes, and changes to internal standard operating procedures, such as changes to procurement or safety management processes. Each of the SMS procedures are equally important and are designed to work together as a system for managing safety risks in a transit agency.

In response to the commenter who encouraged FTA to include Management of Change within the SMS context, FTA makes clear that all of the activities within Safety Assurance—Safety Performance Monitoring,

Management of Change, and Continuous Improvement—are core components of SMS.

Finally, as noted above, under today's final rule small public transportation providers are not subject to the management of change requirements under Safety Assurance. These requirements only apply to rail fixed guideway public transportation systems and FTA recipients and subrecipients that operate more than one hundred vehicles in peak revenue service.

3.3. Safety Assurance: Continuous Improvement

Comments: One commenter sought clarification on the term "continuous improvement," and another commenter recommended replacing the term "continuous" in proposed 49 CFR 673.27(d) with "continual" because "continuous" suggests no room to backslide. Additionally, the commenter suggested replacing the phrase, "If a transit agency identifies any deficiencies . . . , " in proposed 49 CFR 673.27(d)(2) with the phrase, "When a transit agency . . . , " to maintain consistency with the spirit of SMS.

One commenter stated that transit agencies have developed practices for a variety of safety oversight programs to assess and ensure continuous improvement of safety performance. The commenter encouraged FTA to allow transit agencies to continue the development and execution of effective system safety oversight functions, such as safety audits, observations, inspections, assessments, and data analysis, in order to strengthen this component and work towards fully achieving the SMS model.

Response: FTA notes the suggested changes to the verbiage in 49 CFR 673.27(d), but these suggestions are stylistic in nature, and offer no substantive amendments to the regulatory text.

FTA appreciates the commenter who noted the various safety oversight programs that transit agencies have developed over the years to manage safety risk. FTA is providing transit agencies with great latitude and flexibility in developing procedures for managing safety risk, and through the requirements outlined in today's rule, transit agencies should be developing procedures for conducting safety observations, inspections, assessments, and data analysis. FTA expects that the continual efforts tied to safety implementation will improve a transit system's safety performance by reducing, mitigating, and preventing safety outcomes.

Finally, as noted above, under today's final rule small public transportation providers are not subject to continuous improvement requirements under Safety Assurance. These requirements only apply to rail fixed guideway public transportation systems and FTA recipients and subrecipients that operate more than one hundred vehicles in peak revenue service.

4. Safety Promotion

Comments: Several commenters supported the establishment of a comprehensive safety training program, including refresher training, through the Safety Promotion element of SMS. Several commenters provided input on or asked questions about the types of employees who would be subject to training. A few commenters expressed concern with the phrase "directly responsible for the management of safety," asserting that this language is vague and could be interpreted inconsistently. One commenter stated that FTA should replace this phrase with the terminology in FTA's proposed **Public Transportation Safety** Certification Training Program rule at 49 CFR 672.13, which requires transit agencies to "designate its personnel who are directly responsible for safety oversight and ensure that they comply with the applicable training requirements." Another commenter expressed concern that this phrase could be misinterpreted by transit agencies to imply that only management or safety department employees would be subject to a comprehensive safety training program. The commenter suggested that safety training should include all levels of employees at a transit agency and recommended that FTA change this language to cover all employees and contractors. One commenter, however, stated that transit agencies should not be required to train contractors. Another commenter suggested that the terminology used to describe categories of employees is not consistent with the terminology used in 49 CFR part 674, without qualification. Another commenter stated the rule should specify that the training program should apply to the Accountable Executive.

Several commenters recommended that FTA not apply the training requirements to Section 5310 and Section 5311 operators, arguing that the development and implementation of a training program would be a financial and administrative burden. These commenters suggested that FTA should only mandate driver safety training for these operators. Another commenter indicated that live, face-to-face training

is preferred, but noted that this type of training is difficult to schedule and suggested that FTA provide online training and host workshops for the industry.

Several commenters requested additional clarification regarding the proposed training provisions. One commenter asked if FTA would "grandfather" in existing agency safety training programs. Another commenter asked what constitutes a "comprehensive safety training program" and whether FTA foresees any minimum requirements for this program. Another commenter asked whether FTA would provide further guidance on the specific types of safety training that it would require. One commenter believed that FTA's intent is to create a single, comprehensive training program, but references to training throughout the rule make that unclear. One commenter suggested that Safety Promotion could include certifications and evaluations, including a driver report card and/or a professional transit driver program.

Response: FTA appreciates the comments that it received supporting the safety training program. FTA emphasizes that this program is a statutory requirement under 49 U.S.C. 5329(d)(1)(G), which requires each operator of a public transportation system to establish "a comprehensive staff training program for the operations personnel and personnel directly responsible for safety" and includes "completion of a safety training program" and "continuing safety education and training."

Given the unique operating environments and operating systems of each transit agency, FTA is providing great latitude and flexibility in complying with these provisions. Each transit agency should determine for themselves the classes of employees who are directly responsible for safety in that unique system. These employees could include vehicle operators, maintenance staff, dispatchers, the Chief Safety Officer, the Accountable Executive, and other agency staff and management who have direct responsibility for safety. The training program should cover all levels of employees and contractors, and FTA disagrees with the commenter who suggested that these provisions should not apply to contractors. In many systems, contractors have direct responsibility for safety, particularly in circumstances where a transit agency contracts for service, and it is critical that these individuals have training in safety.

In response to the commenters who recommended that FTA not apply the training requirements to Section 5310 and Section 5311 operators, FTA notes that it is deferring regulatory action regarding the applicability of this rule to these recipients and subrecipients until a later time. FTA is providing the industry with template safety plans and training courses, including online training courses, to assist small and large transit agencies with the development of training programs.

In response to the question regarding whether FTA would "grandfather" in existing safety training programs, FTA does not find a need to do so. Certainly, transit agencies can use existing safety training programs, or augment those programs, so long as they meet the requirements in this rule. FTA is not issuing any prescriptive requirements regarding these training programs because it does not believe that a onesize-fits all approach is appropriate. FTA agrees with the commenter who suggested that Safety Promotion could include certifications and evaluations, including a driver report card and/or a professional transit driver program, although FTA is not requiring this type of documentation. Ultimately, each transit agency must determine what is best for its system. Finally, FTA agrees with the commenters who stated that the language in this section could be "misinterpreted by transit agencies to imply that only management or safety department employees would be subject to a comprehensive safety training program" and does intend to create confusion between today's rule and the Safety Certification Training Program rule. Therefore, FTA is updating the language in 49 U.S.C. 673.29 to state: "A transit agency must establish and implement a comprehensive safety training program for all agency employees and contractors directly responsible for safety in the agency's public transportation system.'

5. Scalability of SMS

Comments: Many commenters requested guidance and technical assistance on how SMS could be scaled for small transit providers. One commenter urged FTA to keep guidance and templates at a high level so that they can be tailored to fit the unique needs and circumstances of the broad range of transit agencies subject to the PTASP rule.

Several commenters stated that an appropriately scaled safety plan is particularly important in a zero fatality environment, and FTA should clarify that the transit agency, or the State, is responsible for deciding how to scale

the plan. These commenters suggested that FTA revise 49 CFR 673.21 by replacing "appropriately scaled" with "appropriately scaled by the provider, or if applicable, the State."

One commenter urged FTA to emphasize in the final rule that SMS provides flexibility and adaptability, and it urged FTA to avoid developing prescriptive and restrictive standards for transit agencies that may create major program gaps and limitations. Similarly, another commenter stated that FTA should allow for local choice in implementing SMS plans and programs, asserting that local flexibility would lead to greater and more comprehensive safety plans across individual systems.

Several commenters suggested that the rule lacks detail, and they indicated that FTA should add more detail to the various processes and procedures required, and that FTA should develop templates and associated technical assistance manuals where the requirements could be presented differently based on size, mode, and safety record. One commenter appreciated FTA's efforts to create a rule that considers each transit agency's uniqueness; however, this commenter concluded that the final rule should include identifiable and clearly stipulated requirements which can then be tailored to the individual characteristics of a transit agency.

Response: FTA appreciates the comments that it received regarding the need for technical assistance, guidance, and templates for safety plans. Concurrent with this final rule, FTA is issuing a safety plan template for the industry. FTA is not requiring transit agencies to use the template, but rather, FTA is releasing it as a guide to assist States and transit agencies with the development of their safety plans. Ultimately, each operator of a public transportation system must decide for itself the processes and procedures within the SMS framework that are most appropriate for its unique operating environment. A small bus operator may have simpler processes and procedures than a large rail operator. In situations where a State is drafting a safety plan on behalf of a small public transportation provider, the State and the small public transportation provider should work together and collaborate on the development of processes and procedures that are most appropriate for the operator.

FTA appreciates the comments noting the flexibility and adaptability of SMS, which FTA has emphasized throughout this rulemaking. FTA has taken great efforts to avoid the development of prescriptive and restrictive standards for

transit agencies that may create major program gaps and limitations.

Finally, FTA believes that the requirements in the rule satisfy the minimum requirements of the statute at 49 U.S.C. 5329(d), and if the requirements were any more prescriptive, transit agencies would not have the flexibility that they need to tailor their safety plans to their unique operating environments. If this were the case, the safety plans would be more difficult to develop, and ultimately, less useful in mitigating and preventing safety events. FTA believes that today's rule strikes an appropriate balance in providing a general framework for safety plans and for allowing flexibility and scalability for each individual transit agency.

6. SMS and Safety Culture

Comments: A few commenters emphasized the need for communication between management and agency staff, and they noted the need for a healthy safety culture. One commenter supported the requirement that transit agencies use SMS principles to help achieve a high level of safety, and noted that, to achieve a high level of safety, management at transit agencies must listen to and incorporate the input from their frontline workers and their unions who have daily, firsthand experiences and in-depth knowledge of the transit systems. One commenter acknowledged that training and communication are key components of an effective SMS, but also noted that listening to employees, seeking their feedback, and ensuring a positive culture of safety in their work are also important components of SMS. Another commenter stated that local unions may present administrative challenges in adopting a positive and healthy safety culture.

Response: FTA appreciates the comments that it received regarding the need for a positive and healthy safety culture, and each of the requirements of this rule is designed to help ensure a positive safety culture at each transit agency. FTA wholeheartedly agrees that communication between management and staff, including labor unions, is critical in achieving a positive and healthy safety environment and in reducing safety events. One of the key requirements in today's rule is an employee reporting program, which will allow the frontline staff who have indepth knowledge of the transit system to report unsafe conditions to management without fear of reprisal. FTA believes that these programs will help support a positive safety culture within transit organizations.

J. Safety Plan Documentation and Recordkeeping

1. Safety Plan Documentation

Comments: Two commenters recommended that transit agencies should keep their safety plan documents for more than three years. One of these commenters recommended that transit agencies be required to retain documentation for a minimum of fifteen years, or at least five triennial review cycles. Another commenter asserted that the data contained in the safety plan documentation would be valuable in determining historical trends in a transit agency's safety performance over time, so extending the minimum retention period would allow for more robust historical assessments.

Response: FTA recognizes the value associated with having access to years of data to assist with assessing historical trends. However, such a requirement must be balanced against the costs associated with maintaining such data over an extended timeframe as suggested by the commenter. With that in mind, FTA believes its proposal that transit agencies maintain documents required by this part for a minimum of three years is reasonable relative to cost and effort, and also aligns well with the three year period for Triennial Reviews and State Management Reviews. This requirement would not bar those transit agencies desiring to maintain documents beyond three years from doing so, and FTA would encourage this practice. Accordingly, the proposed three year minimum requirement is included in the final rule.

2. Safety Plan Records

Comments: Several commenters asked which records should be maintained related to training. One commenter asserted that employee training records under the Public Transportation Safety Training Certification Program are already stored in FTA's training portal. Another commenter stated that its agency maintains a Learning Management System to schedule and track training, and this commenter questioned whether this existing system is sufficient or whether the agency will need to keep additional records. One commenter urged FTA to require transit agencies to maintain additional records beyond what is required in the proposed rule.

One commenter requested clarification on whether the requirements to keep training records apply to locally operated transit systems. One commenter stated that it will maintain records on the SMS

requirements for transit agencies that utilize a safety plan drafted by a State.

Response: FTA notes that the training required under the Public Transportation Safety Certification Training Program at 49 CFR part 672 is required of those who are "directly responsible for safety oversight" of the public transit system. FTA has developed a web portal to maintain the training records for those subject to the requirements of that rule. Today's final PTASP rule requires the development of a comprehensive staff training program for operations personnel and personnel who are "directly responsible for safety." Thus, there are two different types of safety training requirements, applicable to different employees of a transit system.

The requirements of today's final rule include the completion of a safety training program and continuing safety education and training. Such training may or may not also include training requirements in accordance with the Public Transportation Safety Certification Training Program Rule at 49 CFR part 672. FTA emphasizes that each transit agency will have discretion and flexibility with regard to the requirements of the safety training program under this part. FTA encourages transit agencies to maintain training records to the maximum extent practicable, but in today's final rule, FTA is not requiring transit agencies to maintain these records and it has removed Section 673.33 "Safety Plan Records" in its entirety for all transit agencies. Specifically, transit agencies are not required to maintain records of safety risk mitigations, results from safety performance assessments, and employee training. FTA believes that this revision from the NPRM to the final rule responds to the industry's concerns regarding recordkeeping and it significantly will reduce the administrative and financial burdens for all transit operators.

3. Other Comments on Documentation and Recordkeeping

Commenters: Numerous commenters stated that transit agencies need data protection for the information in their safety plans. The commenters argued that SMS, by its nature, requires full and open review, evaluation, and prioritization of risk, and the possibility that these safety reviews could be released through the Freedom of Information Act (FOIA), State sunshine laws, or obtained through judicial proceedings serve as a barrier to well-documented and robust self-examination. The commenters encouraged FTA to state its intent to

protect agency analyses to the full extent possible and pursue full authority to exempt safety analyses from discovery and use in judicial proceedings. One commenter suggested that FTA incorporate a confidentiality provision into the rule similar to the provisions in the old SSO rule at 49 CFR part 659.

One commenter suggested that the rule should acknowledge disclosure laws differ between States and that the rule should be written so that transit agencies are not required to disclose records to plaintiffs or allegedly injured parties if a State law does not require them to do so.

Response: When FTA first promulgated its SSO rule in 1995, FTA recognized that rail transit agencies often face litigation arising from accidents, and that the release of accident investigation reports can compromise both the defense of litigation and the ability of agencies to obtain comprehensive, confidential analyses of accidents. Thus, the former SSO rule at 49 CFR 659.11 provided that a state "may withhold an investigation report that may have been prepared or adopted by the oversight agency from being admitted as evidence or used in a civil action for damages." Courts are left to determine whether to admit investigation reports into evidence for litigation, in accordance with the relevant State law and the courts' rules of evidence.

Unlike NTSB accident reports, which cannot be admitted into evidence or used in civil litigation in a suit for damages arising from an accident, there is no such protection for data under FTA's safety rules (see 49 U.S.C. 1154(b) regarding NTSB investigations). Rather, States may enact statutes regarding the admissibility into evidence of accident investigation reports or safety data and analysis conducted in compliance with FTA requirements. FTA emphasizes that any protections must be based on State, not Federal, law and rules of evidence.

With regard to safety records in the possession of FTA, FTA will maintain the confidentiality of accident investigations and incident reports to the maximum extent permitted under Federal law, including the various exemptions under FOIA. Documents submitted to FTA are subject to FOIA and are generally releasable to the public upon request. However, unlike other Federal safety regulatory agencies such as FRA and FAA, Congress has yet to provide FTA with statutory authority to otherwise exempt safety-related information from disclosure. Section 3021 of the FAST Act authorized FTA to undertake a study to determine

whether data protection is necessary. FTA notes that its confidential treatment of information would not preempt State law; therefore, transit agencies still would be required to comply with their State's laws regarding the treatment of such information and should exercise their use of this provision accordingly.

4. Database Systems

Comments: One commenter expressed concern over integrating existing database systems and requested clarification from FTA on how to do so. The commenter urged FTA to clarify which data categories FTA expects to add to existing databases to capture information, and provide additional information on how it will support additional data management systems that agencies will need to acquire as a result of the rule.

Response: Each transit agency will have to determine for itself how it will integrate databases. FTA supports the use of data management systems if a transit agency determines that these systems are necessary to manage safety risks. However, FTA does not foresee transit agencies having to integrate or create new databases, necessarily, in order to comply with the requirements of 49 CFR part 673.

5. Staffing and Resources as a Result of Documentation and Recordkeeping

Comments: Two commenters expressed concern that the documentation and recordkeeping requirements in the proposed rule will produce a need for additional staffing and stretch already limited resources. The commenters stated that recordkeeping and documentation must be scalable.

Response: FTA understands that agencies will need to expend resources to comply with the documentation requirements. FTA has sought to minimize the rule's paperwork burdens and agrees that such requirements for documentation and recordkeeping must be scalable. To this end, FTA has eliminated many of its proposed recordkeeping requirements in their entirety. Specifically, transit agencies are not required to maintain records of safety risk mitigations, results from safety performance assessments, and employee training. FTA believes that this revision from the NPRM to the final rule responds to the industry's concerns regarding recordkeeping and it significantly will reduce the administrative and financial burdens for all transit operators. FTA reiterates that service providers within the public transportation industry can vary greatly

based on size, complexity, and operating characteristics. Transit agencies need safety processes, activities, and tools that scale to the size, complexity, and uniqueness of their systems, and SMS provides such an approach. Therefore, FTA believes that the documentation that is kept for a smaller bus agency may be less voluminous and less complex than those of large rail or multi-modal transit agencies. Moreover, FTA is issuing a safety plan template concurrent with the issuance of this final rule. This template will reduce the burden on transit agencies in developing the documentation necessary (that is, the safety plan) to comply with this rule.

K. Funding

Comments: Several commenters asserted that the proposed rule results in additional costs relating to, among other provisions, reviews, training, software or software upgrades, and the scalability and implementation of SMS. The commenters expressed concern that these additional costs may impact their limited available resources and expressed concern that no additional resources would be provided to support the costs of achieving compliance. Several commenters remarked that this rulemaking seems like an unfunded mandate. These commenters also asked whether there would be additional Federal resources provided to implement the new safety plans. Another commenter asserted that costs related to oversight responsibilities should be eligible for reimbursement by States.

Response: FTA recognizes there are costs associated with implementing the requirements of this rule; however, this rule is a requirement of 49 U.S.C. 5329(d). FTA recognizes the need for increased investments in transit, but Congress determines the specific levels of funding available to FTA recipients. To this extent, FTA disagrees with those commenters who suggested that these requirements are an unfunded mandate. States and operators of public transportation systems may use Federal funding provided through the existing Section 5303, Section 5304, Section 5307, Section 5309, Section 5310, Section 5337, and Section 5339 programs to comply with the requirements in this rule, that is, developing and implementing their safety plans. Costs related to oversight by SŠŌAs are eligible for Federal reimbursement through the State Safety Oversight Grant Program created by 49 U.S.C. 5329.

In an effort to further reduce the administrative, financial, and regulatory

burdens on recipients, FTA will provide technical assistance in the form of templates and guidance documents to assist with the development of safety plans. FTA also is providing training courses to assist the industry with compliance with this rule. FTA has removed Section 673.33 "Safety Plan Records" from the final rule in response to comments from the industry and to reduce costs for individual transit systems. FTA is deferring action regarding the applicability of this rule to the smaller recipients and subrecipients that only receive Section 5310 and/or Section 5311 funds so that it can evaluate additional information and safety data to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

L. Staffing

Comments: Several commenters expressed concerns about the limited staff of many transit agencies and asserted that compliance with the proposed rule, notably the administrative requirements, would require agencies to hire more staff, including contractors or expert consultants, thus increasing costs. One commenter expressed that mediumsized transit agencies may have difficulty absorbing the costs that may be necessary to hire more than one individual without additional funding. One commenter expressed concern that placing increasing requirements on State Department of Transportation staff could create unintended consequences, such as a reduction in work quality or causing staff to forego other critical work.

Response: FTA understands the concerns expressed by some commenters about the staffing resources needed to comply with the rule. Irrespective of the Federal funding stream, FTA continues to believe the scalability and flexibility in safety plan development will not unduly burden any particular transit agency. Given the scalability of SMS, transit agencies may have to reorganize existing staffing resources instead of hiring additional ones. Moreover, to reduce staffing burdens on transit agencies and States, FTA is issuing a safety plan template concurrent with this final rule. In accordance with 49 U.S.C. 5329(d), FTA also is requiring that States draft and certify plans on behalf of small public transportation providers which will further reduce the burden on smaller agencies. FTA is deferring action regarding the applicability of this rule to smaller recipients and subrecipients that only receive Section 5310 and/or

Section 5311 funds so that it can evaluate additional information and safety data to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

M. Enforcement and Oversight

1. Triennial Reviews and State Management Reviews

Comments: A few commenters preferred FTA's review of safety plans as part of the existing Triennial Review and State Management Review oversight processes, rather than annual reviews. One commenter asked FTA to provide more clarity on the State Management Review process. One commenter suggested that FTA could utilize findings from these oversight reviews for purposes of informing the transit industry on safety trends and best practices.

A few commenters expressed concern that FTA may conduct oversight and enforcement of this rule outside of the traditional Triennial Review and State Management Review processes, but FTA did not explain how this additional oversight may impact transit agencies and SSOAs. The commenters recommended that FTA issue guidance explaining this additional oversight so that States, SSOAs, and transit agencies can effectively anticipate and respond to this process, and so that FTA may administer it consistently nationwide. Commenters suggested that FTA should detail procedures for additional reviews or audits outside the normal review schedule, including an advanced notice process and an identification of roles for the SSOAs.

One commenter asked whether and to what extent reviewers could reject performance targets during the Triennial Review process. Another commenter asked about the consequences of a transit agency's failure to meet its safety goals.

Response: As a preliminary matter, pursuant to the statutory provisions of 49 U.S.C. 5329(d)(1)(D), each operator of a public transportation system is required to conduct an annual review and update of its safety plan. This annual review and update is a process to be undertaken by each transit agency independent of the triennial oversight process conducted by FTA. FTA will issue future guidance on any changes to the Triennial Review and State Management Review processes, including the role of an SSOA, to the extent necessary. FTA will not use the National Public Transportation Safety Plan to inform the industry how it will

conduct the Triennial Review or State Management Review processes.

FTA will conduct additional oversight and enforcement of this rule outside of the Triennial Review and State
Management Review processes as necessary and appropriate. FTA notes that its new Public Transportation
Safety Program rule at 49 CFR part 670 outlines its authority to conduct investigations, inspections, audits, and examinations on transit systems. FTA will make oversight and enforcement determinations on a case-by-case basis.

Finally, FTA Triennial and State Management reviewers will not "reject" a transit agency's safety performance targets; however, they will ensure that each transit agency has identified safety performance targets based on the safety performance measures established in the National Public Transportation Safety Plan. To the extent that a transit agency does not meet its safety goals, then using its safety plan as guide, the transit agency must determine for itself which efforts it must undertake to do so.

2. State Oversight

Comments: One commenter stated that a State may reasonably be required to provide oversight in drafting a safety plans, but for some States with multiple responsibilities and multiple recipients and subrecipients of Section 5310 and Section 5311 funds, the additional responsibility of oversight of small Section 5307 operators could be daunting. One commenter remarked that incorporating oversight of public transit systems into the existing SSO program would require additional trained personnel.

Response: As discussed above, FTA is not requiring States to provide oversight of safety plans. States only are required to draft and certify the safety plans on behalf of small Section 5307 operators (unless the operator decides to draft and certify its own safety plan). FTA is responsible for providing oversight and enforcement of all safety plans, and it will utilize the existing Triennial Review and State Management Review processes to do so (with the exception of SSOAs, which have primary safety oversight and enforcement responsibility over rail transit systems). To ease the burden on States, FTA is issuing a safety plan template with this final rule. Also, as discussed above, there is no Federal legal authority for an SSOA to provide safety oversight of a bus system, and this rule does not contemplate an SSOA taking on that role.

3. Other Comments

Comments: One commenter encouraged FTA to provide standard thresholds that it would use to determine the need for a safety audit, this way, FTA would not appear to be arbitrary or inconsistent. This commenter also recommended that FTA provide each transit agency with the opportunity to answer questions and provide additional information to assist safety oversight reviewers.

One commenter asked if FTA would analyze the public's role in collisions rather than concentrating its oversight on transit agencies, arguing that, without addressing the public's interaction with the transit system, transit agencies may risk Federal funding if they do not meet their safety performance targets. Additionally, the commenter asked if FTA would have funding available for purposes of education (internal and external to include educating the public on safety), engineering (highway and vehicle designs), and enforcement if a transit agency fails to meet its safety performance targets.

Response: Through MAP–21 and the FAST Act, Congress provided FTA with significant authority to conduct oversight, inspections, investigations, audits, examinations, and testing, as well as enforcement actions. (49 U.S.C. 5329(f)–(g)). FTA has issued a new regulation at 49 CFR part 670 entitled the "Public Transportation Safety Program" rule. FTA directs readers to that rulemaking for issues related to safety audits conducted by FTA.

FTA has identified NTD reporting thresholds for an "Incident," and those thresholds can be found in Appendix A to FTA's new SSO rule at 49 CFR part 674 (https://www.gpo.gov/fdsys/pkg/FR-2016-03-16/pdf/2016-05489.pdf). These thresholds do not limit FTA's authority to conduct a safety audit in the case of an Incident.

FTA notes that the statutory framework of 49 U.S.C. 5329(d) authorizes FTA to regulate operators of public transportation systems, not the riding public. Nevertheless, through the SMS framework, each transit operator is required to develop processes and procedures for addressing safety risks in all aspects of their systems, and therefore, they must consider the public's role and interaction with their systems when identifying hazards and evaluating risks.

Finally, as discussed throughout this final rule, FTA does not have control over its annual funding levels and appropriations. However, FTA supports the use of Federal funding for purposes

of education, engineering, and enforcement activities, and these types of activities may fall within the scope of eligibility for various funding programs under 49 U.S.C. Chapter 53.

N. NTD Reporting

Comments: One commenter recommended that FTA continue collecting additional safety reporting data through existing programs such as the NTD, which is currently used by transit agencies to report safety incidents.

Another commenter remarked that 49 CFR part 673 does not discuss reporting to FTA through NTD. Additionally, the commenter asked if FTA intends to substantially change the NTD reporting requirements upon the effective date of the proposed PTASP rule.

Response: During this rulemaking, FTA issued a "Notice of Request for Comments on Updates to National Transit Database Safety Information Collection" (https://www.gpo.gov/fdsys/ pkg/FR-2014-08-21/pdf/2014-19787.pdf). FTA issued a "Supplemental Notice and Response to Comments on National Transit Database" (https://www.gpo.gov/fdsys/ pkg/FR-2015-11-18/pdf/2015-29384.pdf). FTA issued final reporting requirements on July 26, 2016, and they are available here: https://www.gpo.gov/ fdsys/pkg/FR-2016-07-26/pdf/2016-17075.pdf. Through today's final rule, FTA is not requiring any reporting of any information to any entity.

O. Security

Comments: Several commenters expressed concerns that the proposed rule did not address security, including terrorism, trespassing, vandalism, assaults, robberies, and cyber threats on transit systems. One commenter suggested that FTA address security and safety of the general public in this rule.

One commenter stated that the TSA is unable to establish cybersecurity requirements for transit control systems due to lack of funding and expertise. This commenter warned that the U.S. Department of Transportation's focus on transportation safety must include an emphasis on transportation control system security to guarantee the safety of associated transportation systems.

One commenter stated that FTA should provide direction regarding security and terrorism preparedness, noting that these preparations should be coordinated with TSA.

Response: As a preliminary matter, TSA has the prerogative and responsibility for all rulemakings on security in public transportation. Specifically, under the Implementing

the Recommendations of the 9/11 Commission Act of 2007 (Pub. L. 110-53), the September 2004 Memorandum of Agreement between DOT and DHS, and the September 2005 modal annex between FTA and TSA, DHS is tasked with the responsibility for carrying out a national strategy for public transportation security to minimize security threats and to maximize the ability of public transportation agencies to mitigate damage from terrorist attacks and other major incidents. While this legislation and these agreements do not preclude transit agencies from implementing measures securing their assets, FTA is not requiring agencies to do so through this final rule. FTA recognizes, of course, that some of the steps that a transit agency takes to ensure the personal safety and security of its riders and employees will overlap with steps it takes to secure its system from a terrorist attack; for example, the steps an agency takes may be part of a threat and vulnerability assessment. FTA notes that a transit agency's expenses for safety and security will continue to be eligible for Federal reimbursement under 49 U.S.C. Chapter

P. SSPP-PTASP Crosswalk

Comments: Although not a part of the PTASP NPRM, several commenters provided input on FTA's "Crosswalk Matrix: 49 CFR part 659.19 System Safety Program Plan Requirements with Proposed Requirements for Public Transportation Agency Safety Plans," which it uploaded onto the docket for this rule. FTA intended this document to provide additional guidance to rail transit systems as to how the 21 elements of an SSPP would fit within the new regulatory requirements for a PTASP.

Several commenters expressed concerns that the crosswalk lumps some SSPP elements into a few categories for PTASPs, and these commenters asserted that the six most complicated SSPP elements are listed under multiple pillars of SMS. A few commenters asserted that some of the 21 elements of SSPPs fit into other pillars of SMS. One commenter encouraged FTA to work with rail transit systems to better align this matrix and promote a better understanding of SMS. One commenter suggested that performance targets should be listed under Safety Assurance, rather than Safety Management Policy. Another commenter provided several detailed suggestions for revised mapping of the SSPP elements with SMS.

Response: FTA agrees that the new PTASP places the former elements of

SSPPs into fewer categories, and this is a result of a new statutory framework under 49 U.S.C. 5329. The statutory provisions of 49 U.S.C. 5329(d) provide specific requirements for PTASPs, and through the design of the new PTASP rule, FTA's intent is to ensure that rail transit systems will not become less safe than they were under the former SSO rule at 49 CFR part 659. Additional, more comprehensive guidance regarding the relationship between SSPPs and PTASPs is forthcoming, and FTA will post that guidance on its website (see https://www.transit.dot.gov/regulationsand-guidance/safety/transit-safetyoversight-tso).

FTA agrees that some of the SSPP elements may be listed under multiple elements of SMS, but FTA believes that this mapping most appropriately connects the PTASP requirements to former SSPP elements. FTA disagrees that safety performance targets should be included under Safety Assurance, rather than Safety Management Policy because safety performance targets guide the safety management decisions, investment decisions, and policy decisions of a transit agency, all critical tenets of Safety Management Policy. Notwithstanding this connection between the former SSPPs and PTASPs, FTA only is requiring transit agencies to set safety performance targets as part of the "General Requirements" section of this final rule (49 CFR 673.11(a)((3)); to avoid redundancy, FTA is not also establishing this requirement in the "Safety Management Policy" section, although, transit agencies may include safety performance targets in their Safety Management Policies if they so choose.

Q. Safety Performance Measures

Comments: Several commenters urged FTA to revise the performance measures proposed in the National Public Transportation Safety Plan. Multiple commenters urged FTA to delete the proposed "reliability" performance criterion for the following reasons: Transit agencies currently do not report reliability data to NTD; the reliability performance measure is redundant of the TAM rule; reliability is a maintenance-related measure, not a safety measure; reliability is not easily quantified; and reliability could vary considerably between transit agencies.

One commenter sought further guidance regarding FTA's four proposed safety performance measures. This commenter suggested that without additional detail, transit agencies would not be able to determine the standards by which FTA and SSOAs would

measure and evaluate the

appropriateness of the safety performance targets established by the agencies.

Response: FTA appreciates the comments that it received regarding safety performance measures; however, FTA notes that today's rule does not establish safety performance measures—FTA's National Public Transportation Safety Plan establishes the measures. FTA is addressing comments regarding the safety performance measures in the notice and comment process for the National Public Transportation Safety Plan.

R. Technical Assistance and Guidance

Comments: Numerous commenters supported FTA's proposal to issue a safety plan template and to provide technical assistance to industry on the development and implementation of safety plans, particularly to address the scalability of SMS to different transit modes and system sizes.

Some commenters stated that FTA should allow transit agencies to attach an appendix to the safety plan template, which would allow a State to avoid drafting multiple unique plans and capture a few unique issues. Several commenters stated that FTA clearly should allow a State to draft a template statewide safety plan or a series of individual safety plans tailored for each unique transit agency. One commenter stated that a transit agency should have the ability to tailor guidance and templates to its own needs, as long as it satisfies the substantive requirements of the final PTASP rule. Another commenter stated that it was looking forward to receiving implementation and gap analysis checklists.

Several commenters noted that there is no mandated timeframe for when FTA will provide technical assistance tools and urged FTA to provide them in a timely manner. Several commenters urged FTA to make PTASP templates available in advance of any implementation deadline; some commenters urged FTA to make PTASP templates available concurrently with this final rule. One commenter suggested that, if FTA is unable to provide PTASP templates on the day that the final rule is published, then FTA should change the implementation deadline to be one year from the date that FTA issues PTASP templates. Another commenter stated that FTA should refrain from issuing a final rule until FTA develops guidance and PTASP templates. One commenter recommended that FTA provide technical assistance tools to States upon request.

Several commenters requested other forms of technical assistance, including an FTA-sponsored website featuring national-level safety performance measurement data, online training, safety workshops, examples of industry best practices, and lessons learned in implementing SMS.

Response: FTA appreciates the support from commenters regarding its development of a safety plan template and other guidance and technical assistance. FTA recognizes the administrative and financial burdens that this rule may impose on the industry, and FTA intends to reduce these burdens through templates, guidance, and technical assistance. Ultimately, the safety plan template, guidance, and technical assistance will help reduce, mitigate, and eliminate hazards and risks and will help make public transportation safer. For these reasons, today, FTA is issuing a template for safety plans concurrent with the issuance of this rule. The safety plan template is generic, minimalistic, and addresses each of the requirements of today's final rule. States and transit agencies can tailor the template to meet the needs of the numerous unique operating environments across the nation.

FTA is providing deference to States in the development of plans on behalf of operators of public transportation. A State may draft a single statewide safety plan, it may draft a unique safety plan for each individual transit operator, it may develop a generic statewide safety plan with a more tailored appendix outlining various processes and procedures for each unique transit operator, or it may develop another method for complying with the rule, so long as the statewide plan or the individualized plans satisfy each of the elements of this rule and contain each of the required processes and procedures for SMS. Transit agencies are free to tailor guidance and templates to meet their own needs, so long as their safety plans satisfy the requirements of this rule. If a State drafts a statewide safety plan, then each individual operator that it covers should keep its plan on file, and the plan should include the relevant and unique information for that particular operator, such as the names of the Accountable Executive and Chief Safety Officer and the operator's safety performance targets.

FTA notes that it has been developing a website through which it has been providing technical assistance, including information related to safety performance, training, examples of industry best practices, and lessons

learned in implementing SMS. The website is located at the following link: https://www.transit.dot.gov/regulationsand-guidance/safety/transit-safetyoversight-tso. FTA has been uploading information onto this website, including guidance and other forms of technical assistance, as it becomes available. FTA encourages the transit industry to utilize the tools on this website with its development and implementation of successful safety practices, and it also encourages the industry to provide feedback on this website, as it evolves, through the "Contact Us" tool at the following link: https:// ftawebprod.fta.dot.gov/ContactUsTool/ Public/NewRequest.aspx.

Finally, as mentioned above, in an effort to assist the industry with meeting the requirements of this rule, FTA is making the effective date one year after its publication date. As a result, transit agencies will have a total of two years from the publication date to certify that they have safety plans meeting the requirements of 49 CFR part 673.

S. Coordination With Other Entities

Comments: Two commenters expressed concern with the potential for inconsistency and duplication between FTA and FRA safety regulations. One commenter urged FTA to coordinate its NTD with FRA's Accident/Incident Report Generator.NET (AIRGNET) to establish consistent terminology, reporting requirements, audit requirements, training requirements, and safety plan requirements.

One commenter recommended that FTA adopt safety standards and methodologies developed by the U.S. Department of Defense, including system safety analytical methods to assess hazards and consequences and system safety engineering principles and techniques to develop and design mitigation. Two commenters encouraged FTA to establish an advisory committee of transit operators to assist with the development of policies and procedures for smaller operators.

Response: FTA makes clear through today's rule that transit agencies that operate a rail fixed guideway public transportation system subject to regulation by FRA do not have to develop safety plans for that mode of service. 49 CFR 673.11(f). FTA does not intend to issue safety regulations that conflict or are inconsistent with FRA's safety regulations, and to that end, FTA has coordinated and will continue to coordinate with FRA on the development and implementation of this rule. FTA also has taken great efforts to ensure that terminology,

definitions, reporting requirements, training requirements, and regulatory enforcement efforts are consistent with other Federal safety and reporting regulations to the maximum extent possible.

FTA appreciates the suggestion that it should adopt safety standards and methodologies developed by the U.S. Department of Defense, including system safety analytical methods to assess hazards and consequences and system safety engineering principles and techniques to develop and design mitigations; FTA is adopting the SMS approach to addressing safety risk, which is consistent with the approach taken by other modes within the U.S. Department of Transportation.

Finally, as FTA develops and issues guidance and best practices for safety, FTA intends to consult with the transit industry, including the Transit Advisory Committee for Safety, to the maximum extent practicable.

T. Nexus Between the PTASP Rule and Other FTA Requirements

Comments: Numerous commenters suggested that FTA clarify the nexus between the PTASP rule and other related FTA requirements, specifically, the National Public Transportation Safety Plan, the SSO rule, the Safety Certification Training Program rule, the Bus Testing rule, and the Transit Asset Management rule. These commenters recommended that FTA clearly define the link between the PTASP rule and other FTA requirements, especially the Transit Asset Management rule, to be consistent to avoid conflicting regulations. One commenter recommended that, to foster a strong culture of safety, FTA should extend data protection to asset management analyses.

One commenter urged FTA to reinforce the link between the PTASP rule and the SSO rule, arguing that FTA should work to strengthen and streamline the mitigation, reporting, and notification processes.

Response: FTA appreciates the comments that it received regarding the connection between the PTASP rule and other related FTA regulations. With respect to the National Public Transportation Safety Plan, FTA emphasizes that the Plan establishes safety performance measures to which each operator of a public transportation system must set performance targets in their safety plans, as required in the PTASP rule.

In the SSO rule, FTA requires each SSOA to develop a program standard which, among other things, establishes minimum safety standards for the safety

of all rail fixed guideway public transportation systems within its jurisdiction. FTA also requires each SSOA to approve the PTASP of every rail fixed guideway public transportation system within its jurisdiction. Each SSOA should review those safety plans to ensure that they are compliant with the PTASP rule, the National Public Transportation Safety Plan, and its own program standard. FTA notes that the PTASP rule does not add any additional notification or reporting requirements; those requirements are outlined in the SSO rule and the NTD Reporting Manuals.

In the Safety Certification Training Program rule, FTA establishes minimum training requirements for transit agency employees and contractors who are directly responsible for safety oversight of rail fixed guideway public transportation systems that receive FTA funds. In the PTASP rule, FTA requires each operator of a public transportation system to establish a comprehensive safety training program for all employees and contractors directly responsible for safety. In this section of the safety plan, a rail transit system also may include its training program for employees and contractors who are directly responsible for safety oversight.

In the Bus Testing rule, FTA requires recipients of FTA funds to test buses to ensure that they meet minimum performance standards, a scoring system, and a pass/fail threshold if they are using FTA funds to procure the buses. This rule exists separate and apart from the PTASP rule, but transit agencies may incorporate by reference into their safety plans any processes and procedures that they utilize for bus testing pursuant to the Bus Testing rule.

Finally, in the Transit Asset Management rule, FTA requires transit agencies to conduct asset inventories and then perform condition assessments on their assets. Those condition assessments should inform the SMS activities that a transit agency undertakes pursuant to its safety plan. To illustrate how these rules work together, if a transit agency finds through a condition assessment that an asset is not meeting its state of good repair standards, then the transit agency may conduct safety hazard identification and safety risk assessment analysis on that asset. The transit agency may mitigate any safety risks, as necessary, and it may reprioritize its capital plan in accordance with the FTA and FHWA Planning rule at 23 CFR part 450. FTA notes that it addressed any comments related to asset management in the final Transit Asset Management rule.

U. Americans With Disabilities Act Issues

Comments: One commenter stated that the proposed rule should not conflict with the Americans with Disabilities Act laws and regulations, and vice-versa. The commenter urged FTA to clarify how it will treat safety issues and incidents that may conflict with ADA requirements, remarking that agencies should not be subject to inspections, audits, examinations, investigations, directives, or other possible sanctions for adhering to ADA requirements.

Response: FTA does not intend the PTASP rule to conflict with the ADA and its implementing regulations, which are designed to prevent and eliminate discrimination. Nevertheless, to the extent that a transit agency is undertaking action to comply with the ADA—such as the construction of capital projects to make facilities ADAcompliant; the installation of accessible features on vehicles, platforms, and other transit facilities; and the provision of paratransit service—FTA expects that action to be undertaken safely and in accordance with this final rule and a transit agency's safety plan.

V. Other Comments on the Rule

Comments: One commenter suggested that all transit agencies should have safety plans only for maintenance and training, and that States should review safety plans only if a transit agency has safety issues. One commenter encouraged FTA to incorporate occupational health issues into the rule, focusing on driver assault, restroom breaks, and fatigue management. Another commenter encouraged FTA to join a "Journey to Safety Excellence—a cycle of improvement that aims for a continuous reduction of risk with a goal of zero harm," stating that integrating the principles of the "Journey to Safety Excellence" into workplace safety strategies can make a great difference in saving lives and preventing injuries. One commenter remarked that zero is the only goal that transit agencies should establish in their performance targets.

A commenter expressed disapproval for the guidelines FRA developed for rail vehicle crashworthiness, citing the Union International des Chemins de Fers (UIC), an international rail regulatory body, as an alternative example. This commenter urged FTA to use UIC as an example and expressed hope that FTA can serve as a role model for FRA.

Response: FTA disagrees with the commenter who suggested that all

transit agencies should have safety plans only for maintenance and training, and that States should review safety plans only if a transit agency has safety issues. FTA's authorizing statute at 49 U.S.C. 5329(d)(1)(B) mandates that each operator of a public transportation system establish "methods for identifying and evaluating safety risks throughout all elements of the public transportation system." This requirement would extend beyond mere maintenance and training, and in this final rule, FTA makes clear that transit agencies should address safety risks in all aspects of their systems, including maintenance, training, operations, construction of new facilities, rehabilitation of existing facilities, etc. Moreover, the statutory provisions of 49 U.S.C. 5329(d) require States to "draft" and "certify" safety plans on behalf of small Section 5307 operators. States cannot merely review plans if one of these transit agencies has "safety issues."

FTA appreciates the comment that it received regarding occupational health issues. To the extent that occupational health issues may be safety hazards and present safety risks, transit agencies should be addressing them through the SMS processes outlined in their safety plans. FTA will issue rules regarding operator assault in the future.

Regarding the establishment of "zero" as the only feasible goal in performance targets, FTA only is creating safety performance measures by which transit agencies are to set performance targets. FTA is not mandating any particular goal or target; it is deferring to each transit agency, MPO, and State and to set targets for each of their unique systems and geographical areas.

Finally, FTA notes that this final PTASP rule does not establish guidelines for rail vehicle crashworthiness. Please see the National Public Transportation Safety Plan, available on FTA's website, for more information regarding safety performance standards for public transportation vehicles.

W. Regulatory Impact Analyses

1. Costs

Comments: One commenter concluded that FTA underestimated the costs associated with the implementation of the rule. Similarly, a transit agency estimated cost increases to ensure compliance with the rule.

Several commenters provided specific cost estimates related to the proposed requirements. One commenter remarked that upgrading its surveillance system on buses would cost approximately \$2

million and that it installed driver barriers in 30 new buses, at a cost of \$4,202 per barrier, totaling \$126,060. This commenter stated that the additional recordkeeping could require the purchase of new equipment and tracking software and the hiring and training of additional staff, which would result in costs of at least \$4 million. This commenter asserted that staffing at the administrative level would cost about \$85,000 annually and contractor personnel would cost about \$75,000 annually. This commenter asserted that training for administrative staff would cost about \$30,000 per person, and training for contractor personnel would cost about \$10,000 per person. One commenter estimated that it would cost a State \$200,000 annually to adequately perform any oversight responsibilities. One commenter estimated that its initial investment could reach at least \$1 million for a risk management information system, training, and personnel. One commenter stated that it could not estimate the cost of coordination with MPOs on the establishment of performance targets.

Response: FTA appreciates the comments on the costs of the proposed rule. It is a challenge to develop cost estimates for the rule that can be representative of any one agency given the differences in agency size, modes, location, and level of maturity of safety programs. The regulatory analysis acknowledges that mitigation costs of identified risks are not included in the estimated cost of the proposed rule. The cost of onboard surveillance systems and driver barriers are mitigation costs. Typically, a transit agency makes these types of investment decisions with the understanding that there will be benefits of the mitigation that exceed the costs of the mitigation. Today's rule does not recommend any specific mitigation, and does not require agencies to implement mitigations that have greater costs than benefits.

The annual personnel costs of recordkeeping cited by the commenter are considerably higher than the estimated cost in the proposed rule. FTA's cost estimate for this particular type of agency is \$20,000 for staff; \$15,000 for information technology; and \$4,000 for training, excluding travel costs. FTA cannot estimate costs for specific agencies, since FTA does not know how these costs would vary by size within each category. The larger the agency, the greater the amount of data and records that need to be maintained, with the possibility of significant economies of scale for certain recordkeeping tasks, but increased complexity in others, possibly requiring

more sophisticated systems than those of the smaller agencies. It is possible that a large transit agency may need one additional full time staff and a contractor (at a total cost of \$160,000 per year) to maintain records. Most likely, these individuals would be performing other duties. It also is possible that the initial set up costs may be higher for those who may not have the expertise in this area. FTA does not anticipate that these costs will be continual. Therefore, while FTA accepts that the cost estimates in the NPRM may be low for some agencies, FTA does not believe that the costs would be as high as suggested by the commenter and continuous into the future.

The commenter's estimated cost of \$200,000 for "oversight" is significantly higher than FTA's estimated total State cost estimate of \$18,000. FTA emphasizes it is not requiring States to conduct safety oversight through this rule; FTA is only requiring States to draft and certify safety plans on behalf of particular operators of public transportation systems. Moreover, with today's rule, FTA is providing a safety plan template which significantly will reduce costs to States and operators, particularly for the smaller operators. Therefore, FTA believes that the commenter overestimated the costs significantly.

The commenter's \$1 million estimate for a risk management information system and associated staff may not be unreasonable. FTA estimates annual costs in the range of \$15,000 to \$20,000 for information technology systems for rail transit agencies and for large bus operators that receive Section 5307 funds. FTA estimates additional staff costs for risk assessment and assurance activities of approximately \$60,000 per year for large Section 5307 operators. These costs would total \$1 million over a span of thirteen years, at which time information technology systems may need to be updated. It is possible that the costs would be higher during the initial years and significantly reduced in subsequent years. Also, it is possible that the information technology system will be used for multiple tasks, some of which may not be related to this rule.

2. Benefits

Comments: One commenter questioned what benefit, if any, would be achieved from the rule if FTA is unable to provide evidence to show that the implementation of the rule would increase safety and reduce transit incidents. The commenter asserted that it seems unreasonable to require an "economically significant" expenditure of limited transit agency funds when

funds should be used for state of good repair and transit asset management needs. Another commenter concluded that FTA is premature in estimating economic benefits through the Regulatory Impact Analysis before this rulemaking is effective and implemented.

Ône commenter stated that a positive return on investment (ROI) may not be possible without adequate resources, and this commenter asserted that the NPRM does not specify whether an ROI would exceed a break-even point. The commenter asked to review actual results of implementing SMS to help justify the anticipated level of investment, suggesting that SMS should be piloted in a few transit agencies before being implemented nationally.

Response: As discussed in other sections of this rule and as discussed in more detail below, today's regulatory provisions are required by statute under 49 U.S.C. 5329(d), and FTA is implementing SMS in the least prescriptive way possible.

Safety Management Policy is the foundation of the organization's SMS. The safety management policy statement clearly states the organization's safety objectives and sets forth the policies, procedures, and organizational structures necessary to accomplish the safety objectives. It clearly delineates management and employee responsibilities for safety throughout the organization. It also ensures that management is actively engaged in the oversight of the organization's safety performance by requiring regular review of the safety policy by a designated Accountable Executive (general manager, president, or other person with similar authority). Within the context of the Public Transportation Agency Safety Plan, an organization's safety objectives will be articulated through the setting of performance targets based on, at a minimum, the safety performance measures established in the National Public Transportation Safety Plan. See 49 U.S.C. 5329(d)(1)(E).

Pursuant to the statutory requirements of 49 U.S.C. 5329(d)(1)(B) and (C), each agency's Public Transportation Agency Safety Plan must include "methods for identifying and evaluating safety risks throughout all elements of the public transportation system," and "strategies to minimize the exposure of the public, personnel, and property to hazards and unsafe conditions." Each of these requirements is consistent with the second component of SMS—Safety Risk Management—which requires the development of processes and activities to help the organization better identify

hazards associated with its operational systems. Once identified, a transit agency must evaluate the safety risk associated with the potential consequences of these hazards, and then institute mitigations, as necessary, to control the consequences or minimize the safety risk.

The statutory requirements of 49 U.S.C. 5329(d)(1)(B), (C), and (D)-"methods for identifying and evaluating safety risks throughout all elements of the public transportation system," "strategies to minimize the exposure of the public, personnel, and property to hazards and unsafe conditions," and "a process and timeline for conducting an annual review and update of the safety plan"-encompass the requirements of the third component of SMS: Safety Assurance. Safety Assurance requires an organization to monitor its safety performance, and it is designed to ensure that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of data. Through regular reviews and updates of its safety plan, a transit agency would evaluate changes to its operations that might introduce new safety risks. If a transit agency identifies safety risks through its safety performance assessments, then it must take action to correct any safety deficiencies. All of these efforts are intended to minimize the exposure of the public, personnel, and property to safety hazards and unsafe conditions. To minimize administrative, financial, and regulatory burdens under Safety Assurance, FTA has reduced requirements for small public transportation providers and has developed a minimal set of Safety Assurance provisions under 49 CFR 673.27.

The fourth component of SMS— Safety Promotion—involves the training, awareness, and communication that support safety. The training aspect of SMS is consistent with the statutory requirement of 49 U.S.C. 5329(d)(1)(G) for a comprehensive staff training program for operations personnel and personnel directly responsible for

FTA is intending to implement 49 U.S.C. 5329(d) in the least prescriptive way possible by designing minimalistic regulatory requirements that mirror the relevant statutory provisions. By utilizing SMS in the regulatory framework, transit operators of varying sizes, complexities, and operating characteristics can build safety plans that are flexible and scalable to meet their unique safety needs. Through its scalability, SMS helps reduce the costs and burdens associated with developing

and implementing safety plans. Also, as noted above, FTA eliminated several significant Safety Assurance requirements for small public transportation providers in this final rule.

While FTA is unable to provide definitive evidence that the implementation of this rule would increase safety by reducing incidence of safety events, FTA fully anticipates that safety benefits will be realized if this rule is implemented. By adopting a systematic approach to safety through the development of the safety plan and the practice of SMS, transit agencies are expected to reduce the risk and probability of safety incidents. FTA expects that a proactive approach to managing safety risks is more effective than a reactive approach. The SMS approach to safety, which involves collecting data, predicting and mitigating future safety events, training, accountability, and open communication will reduce safety events and improve safety outcomes in the future. Indeed, state of good repair investments could prevent and mitigate future safety events.

FTA currently is conducting an SMS pilot program at a large multi-modal transit agency and is planning to implement two additional pilot programs for bus agencies to better understand how a transit agency would implement SMS. The results of these pilot programs will help inform FTA's efforts to provide guidance to the industry on SMS implementation. FTA notes that the benefits of SMS implementation may take years to be realized, and in turn, taking time for the benefits of SMS to be fully estimated and quantified.

In light of various public comments, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. FTA is deferring action pending further evaluation of additional information and safety data related to these operators to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

Six years after the compliance date for this rule, FTA plans to prepare a report evaluating the benefits and effectiveness of the regulatory framework provided by this rule. In this report, FTA plans to utilize the results of the pilot program and information gathered from oversight reviews, which will include an evaluation of the flexibility and

scalability of the SMS framework in developing and implementing safety plans. The results in this report will be made available for public comment to help inform any future amendments that may be needed to the regulatory framework that improves the PTASP process and furthers the goal of public transportation safety.

3. Regulatory Flexibility Act

Comments: Several commenters provided input on the rule's impact to small entities. Several commenters asserted that small to medium sized transit agencies face budget constraints and expressed concern that these agencies may need to hire additional staff to comply with the rule or reduce transit service.

Several commenters expressed concern that FTA crafted the NPRM with only rail transit systems in mind. One commenter stated that the excellent safety record of rural transit systems warrants a limited approach to Federal safety regulation regarding rural bus systems, which would enable operators to focus scarce resources on safely delivering transit services, not on regulatory compliance. The commenter warned that if FTA does not tailor the rule to small transit systems, then many small bus operators would have to shift funds and personnel from the actual delivery of service to compliance with safety rules. The commenter asserted that MAP-21 reduced the portion of Section 5311 funds available for program administration from 15 percent to 10 percent. The commenter noted that, in Senate Report 3638, the Senate Committee on Banking, Housing, and Urban Affairs indicated its intent that FTA take a "measured approach," and not a "one size fits all" approach, to

One commenter stated that FTA's Regulatory Flexibility Act analysis is somewhat misleading, particularly where tribal governments are concerned. Due to the modest amount of funding available to tribes, the commenter concluded that the cost associated with developing a safety plan for tribal governments is much higher than FTA's estimate of 0.5 to 1.5 percent; the commenter asserted that the costs are closer to 5.5 to 15.5 percent.

Response: FTA has taken significant efforts to reduce the burden on small transit agencies. For small Section 5307 operators, FTA is requiring States to draft and certify their safety plans. FTA designed the requirements of today's rule, particularly the SMS requirements, to be scalable, flexible, and not prescriptive for small transit operators. Moreover, FTA developed a safety plan template for small operators to assist them with the development of their

plans. FTA is offering live and online training to small transit operators, and it is offering any technical assistance that might be needed. FTA notes that many small transit agencies already have processes and procedures in place that comply with the requirements of today's rule, and given the safety record of many smaller operators, significant mitigation may not be necessary. FTA emphasizes that the statutory requirements of 49 U.S.C. 5329 make the rule applicable to any operator of a public transportation system, and small operators are not excluded from the rule.

To accommodate small public transportation providers and to reduce their administrative, financial, and regulatory burdens, FTA made significant changes to its proposed regulatory framework in the NPRM. FTA eliminated a Safety Assurance requirement for all transit agencies to monitor their operations to identify hazards not identified through their Safety Risk Management processes. Also, FTA eliminated an entire section of recordkeeping requirements related to safety risk mitigation, safety performance assessments, and employee safety training. FTA further tailored the rule for small operators and reduced their requirements under Safety Assurance. Small public transportation providers only need to develop processes for safety performance monitoring and measurement; they do not need to develop processes for management of change and continuous improvement. Through the elimination of these requirements for small public transportation providers, and through this tailored approach, FTA believes that it has reduced their burdens significantly.

Finally, FTA notes that in light of various public comments, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. FTA is deferring action pending further evaluation of information and safety data related to these operators to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

X. Tribal Issues

1. Applicability of the Rule to Tribes

Comments: Several commenters suggested that some tribes operate modest public transportation systems and receive Federal financial assistance through either the discretionary or formula tribal transit programs under 49 U.S.C. 5311. One commenter stated that some tribes receive funds as subrecipients of States under 49 U.S.C. 5311, and therefore, FTA should exclude those subrecipients from this rule. The commenter also requested FTA to clarify the applicability of this rule to tribes. Finally, this commenter recommend that FTA's final rule exempt tribes from the definition of "recipient" under the proposed provisions of 49 CFR 673.1 until FTA has undertaken additional consultation with tribes and develops a template safety plan.

Response: FTA appreciates the commenter who stated that tribes operate modest public transportation systems, and in response, FTA has designed this rule to be as flexible and scalable as possible for smaller operators. In light of various public comments, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds, including tribal transit operators. FTA is deferring action pending further evaluation of additional information and safety data related to these operators to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

FTA has undertaken consultation with tribes throughout this rulemaking, and these efforts are described in more detail below.

2. The State's Role in Tribal Safety Plans

Comments: A few commenters recommended that FTA require tribes to develop their own safety plans, even if they are a State's subrecipients under 49 U.S.C. 5311, unless a State voluntarily agrees to draft and certify a safety plan for a tribal subrecipient. Some commenters expressed concerns that a State's preparation of safety plans for tribes could interfere with tribal sovereignty. One commenter suggested that a State's interaction with a tribe in relation to a safety plan is unwarranted and inconsistent with the laws and treaties that govern the status and protections for tribes. The commenter asserted that the Tribal Transit Program funded under 49 U.S.C. 5311(c) is not a subset of the Section 5311 program; it is a separate and direct tribal program and the rules associated with its administration should be structured accordingly. Several commenters stated that there often are positive relationships between States and tribes, but FTA should not treat tribes as subcomponents of State transit systems given the independent status of tribes.

One commenter expressed concern that FTA would be less willing to provide technical assistance to tribes if States draft and certify their safety plans.

Response: FTA recognizes the administrative and financial burdens that this rule may impose upon smaller transit operators, such as tribes. In an effort to relieve this burden, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds, including tribal transit operators. FTA is deferring action pending further evaluation of information and safety data to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

3. Financial Impact on Tribes

Comments: Several commenters stated that the proposed rule would result in administrative costs to tribes, such as costs for additional staff time and resources. One commenter stated that, like many other smaller transit agencies, tribal transit managers may have many different roles and shared duties, so the requirement for an Accountable Executive may be problematic because the staff are not structured in the way the proposed rule seems to envision. The commenter said that compliance with the rule may require consultants or new staff to handle the extra reporting paperwork and separation of positions, which would be difficult with limited resources. This commenter recommended that FTA should incorporate the following language somewhere into its rule: "at agencies where such delineations exist between administrative positions.'

Several commenters noted that some tribes receive limited funding. One commenter stated that the average annual apportionment for tribal transit agencies is almost \$220,000 and the average annual discretionary award is about \$77,000, and some of 100 tribes participating in the Tribal Transit Program have apportionments as low as \$4,000 annually. Several commenters argued that, for a tribe whose only source of Federal funding for its Tribal Transit Program is a \$25,000 grant, the compliance costs associated with this rule (such as personnel time and the possible need for outside consultants) could easily consume the entire grant. The commenter stated that, although States divide more than \$8.6 billion in Federal transit grants for Federal Fiscal Year 2016, tribes receive only \$30 million under the Tribal Transit

Program and an extra \$5 million for the discretionary Tribal Transit Program under 49 U.S.C. 5311.

Response: FTA acknowledges that many smaller transit operators, including tribes, may experience substantial costs in complying with this rule. In light of the potential financial burden on smaller operators, including tribes, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds. FTA is deferring action pending further evaluation of information and safety data related to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

4. Tribal Consultation

Comments: Several commenters expressed concern regarding FTA's consultation with tribes. Several commenters alleged that FTA conducted no consultation with tribes, including meetings, conference calls, or webinars. Several commenters suggested that FTA conduct additional consultation with tribes, particularly given their smaller sizes.

Several commenters disagreed with FTA's preliminary determination that the rule would not have a substantial direct effect on tribes or impose substantial direct compliance costs on tribes, which is the criteria that would trigger tribal consultation under Executive Order 13175 and the U.S. Department of Transportation's tribal consultation policy. One commenter stated that the rule would have direct effects on tribes by adding regulatory requirements on them, thus changing the relationship between tribes and the Federal government with respect to the inspection, investigation, audits, examinations, and testing of transit infrastructure and rolling stock. This commenter expressed concern that courts have emphasized the need for advance consultation with tribes on rulemaking efforts that may impact them, and cited Wyoming v. Department of the Interior in which the U.S. District Court for the District of Wyoming issued a preliminary injunction against Bureau of Land Management's hydraulic fracturing regulations because the agency failed to adequately consult with tribes.

Another commenter stated that the promulgation of this rule may conflict with the Tribal Self-Governance Program created by the FAST Act, and asserted that the Tribal Self-Governance Program requires a negotiated rulemaking committee to develop rules

and regulations for all modes of funding and U.S. Department of Transportation programs, led by the U.S. Department of Transportation's Deputy Assistant Secretary for Tribal Government Affairs.

One commenter suggested that, instead of requiring States to draft and certify safety plans on behalf of tribes, FTA should work with tribes to develop a model safety plan specifically for tribes.

Response: As a preliminary matter, FTA notes that it conducted extensive outreach with tribes throughout this rulemaking. Specifically, on February 12, 2016, FTA conducted public outreach for tribes and hosted a Tribal Technical Assistance Workshop wherein FTA presented its proposed rule and responded to numerous technical questions from tribes. FTA subsequently delivered the same presentation during a webinar series open to all members of the public on February 24, March 1, March 2, and March 3. On March 7, FTA delivered the same presentation at an outreach session hosted by the National Rural Transit Assistance Program, which also was open to all members of the public. During each of these public outreach sessions and the public webinar series, FTA received and responded to numerous technical questions regarding the NPRM. FTA recorded the presentations, including the question and answer sessions, and made available the following documents on the public docket for this rulemaking (Docket FTA-2015-0021): (1) FTA's PowerPoint Presentation from the public outreach sessions and public webinar series (https:// www.regulations.gov/document?D=FTA-2015-0021-0012); (2) a written transcript of FTA's public webinar of March 1, 2016 (https://www.regulations.gov/ document?D=FTA-2015-0021-0010); (3) a consolidated list of every Question and FTA Answer from the public outreach sessions and public webinar series (https://www.regulations.gov/ document?D=FTA-2015-0021-0041); and (4) the results of polling questions from FTA's public outreach sessions (https://www.regulations.gov/ document?D=FTA-2015-0021-0011). FTA also uploaded onto YouTube an audiovisual recording of its webinar from March 1, 2016. The video is available at the following link: https:// www.youtube.com/watch?v=FBj5HRatw GA&feature=youtu.be.

FTA also notes that, in advance of publishing an NPRM, FTA sought comment from the transit industry, including tribes, on a wide range of topics pertaining to safety and asset management through an ANPRM. In the

NPRM, FTA asked specific questions about how today's rule should apply to tribal recipients and subrecipients of Section 5311 funds.

In light of the comments that FTA received from tribes throughout the rulemaking process, FTA is deferring regulatory action regarding applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds, including tribal transit operators. FTA is deferring action pending further evaluation of additional information and safety data to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

IV. Section-by-Section Analysis

Subpart A—General

673.1 Applicability

This section explains that this regulation applies to all States, local governmental authorities, and other operators of public transportation systems that are recipients and subrecipients of Federal financial assistance under 49 U.S.C. Chapter 53. At this time, the regulation does not apply to an operator of a public transportation system that only receives Federal financial assistance under 49 U.S.C. 5310, 49 U.S.C. 5311, or both 49 U.S.C. 5310 and 49 U.S.C. 5311. In accordance with 49 U.S.C. 5329(d), a Public Transportation Agency Safety Plan is required of all operators of public transportation systems, whereas in the past, a "system safety program plan" only was required of rail fixed guideway public transportation systems, in accordance with the former regulatory provisions at 49 CFR 659.17. Each operator of a public transportation system must comply with today's rule within one calendar year of this rule's effective date.

673.3 Policy

This section explains that FTA is utilizing the principles and methods of SMS as the basis for this regulation and all other regulations and policies FTA has issued and will issue under the authority of 49 U.S.C. 5329, to the extent practicable and consistent with law and other applicable requirements (such as those for regulatory review). FTA's standards for SMS are flexible and scalable and may be tailored to the size and operating complexity of the transit operator.

673.5 Definitions

This section sets forth a number definitions, many of which are based on the principles and methods of SMS.

Most notably, readers should refer to "Accountable Executive," "Hazard," "Operator of a Public Transportation System," "Safety Assurance," "Safety Management System," "Safety Management Policy," "Safety Promotion," "Safety Risk Management," and "Small Public Transportation Provider." In recent years, SMS has emerged as the preferable practice for enhancing safety in all modes of transportation, and the Secretary of Transportation instructed each of the Department's operating administrations to develop rules, plans, and programs to apply SMS to their grant recipients and regulated communities. Many of the SMS-related definitions in § 673.5 are similar to those set forth in FAA's SMS regulation, entitled "Safety Management Systems for Domestic, Flag, and Supplemental Operations Certificate Holders," 14 CFR parts 5 and 119, 80 FR 1308, Jan. 8, 2015.

Additionally, a set of frequently asked questions about SMS are available on FTA's website at http://www.fta.dot.gov/tso_15177.html. FTA is incorporating these same definitions for SMS in its related rulemakings for the Public Transportation Safety Program and the Public Transportation Safety Program, and FTA is incorporating these same definitions into the National Public Transportation Safety Plan.

FTA includes a definition for "Accountable Executive" that identifies the person at a transit agency that has the responsibility and accountability for the implementation of SMS and control and direction of the Public Transportation Agency Safety Plan and the Transit Asset Management Plan. FTA includes definitions for "Safety Risk Management," "Risk," "Safety Assurance," and "Safety Management Policy," all key terms to the implementation of SMS.

This section also defines a number of terms used repeatedly throughout the other safety programs authorized by 49 U.S.C. 5329. Some of these terms are included in FTA's new State Safety Oversight Rule at 49 CFR part 674, which was issued prior to today's final rule. FTA intends to have the same definitions for all terms utilized in its safety programs. Readers should refer, specifically, to the definitions of "Accident," "Event," "Hazard," "Incident," "Investigation," "Occurrence," "Transit Agency," and "Rail Transit Agency." FTA has updated its definitions of "Accountable Executive," "Safety Risk Assessment," "Safety Risk Management," and "Transit Asset Management Plan" to make them consistent with definitions

of these terms utilized in the SSO rule and the Transit Asset Management rule which were issued prior to today's final rule. FTA also added a definition of "Rail Fixed Guideway Public Transportation System," which it defined in its SSO rule.

Pursuant to 49 U.S.C. 5329(d)(3)(B), FTA must issue a rule that designates which 49 U.S.C. 5307 small public transportation providers may have States draft Public Transportation Agency Safety Plans on their behalf. This section defines "Small Public Transportation Provider" (in accordance with 49 U.S.C. 5329(d)(3)(B)) as "a recipient or subrecipient of Federal financial assistance under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in peak revenue service and does not operate a rail fixed guideway public transportation system.'

FTA includes definitions for the terms "National Public Transportation Safety Plan," "Transit Asset Management Plan," and "Equivalent Authority," all of which are consistent with the use of those terms in the statutes and FTA's related rulemakings on safety and transit asset management.

Subpart B—Public Transportation Agency Safety Plans

673.11 General Requirements

This section outlines the minimum elements to be included in a Public Transportation Agency Safety Plan. Pursuant to 49 U.S.C. 5329(d)(1), this section requires each operator of public transportation subject to this rule to develop and certify that it has a Public Transportation Agency Safety Plan consistent with this part. In accordance with 49 U.S.C. 5329(d)(3)(B), § 673.11(d) requires each State to draft the Public Transportation Agency Safety Plan for small transportation providers as defined in today's final rule. A State is not required to develop a Public Transportation Agency Safety Plan for a small public transportation provider if that agency notifies the State that it will develop its own plan.

In accordance with 49 U.S.C. 5329(d)(1)(A), § 673.11(a)(1) requires that each Public Transportation Agency Safety Plan, and any updates thereto, must be signed by the transit agency's designated Accountable Executive and approved by the transit agency's Board of Directors, or an Equivalent Authority. In today's final rule, the accountability for the contents of a Public Transportation Agency Safety Plan is formally elevated to the Accountable Executive and Board of Directors.

In accordance with 49 U.S.C. 5329(d)(1)(B), (C), (D), (E), (F), and (G), a transit agency must establish: Methods for identifying and evaluating safety risks throughout all elements of its public transportation system; strategies to minimize the exposure of the public, personnel, and property to hazards and unsafe conditions; a process and timeline for conducting an annual review and update of its safety plan; safety performance targets; a Chief Safety Officer who reports directly to the general manager, president, or equivalent officer; and a comprehensive staff training program for the operations personnel and personnel directly responsible for safety. These statutory requirements fit into the four key pillars of SMS: Safety Management Policy, Safety Risk Management, Safety Assurance, and Safety Promotion. Consequently, FTA is requiring each transit agency to develop and implement an SMS under § 673.11(a)(2); this SMS will satisfy the statutory requirements of 49 U.S.C. 5329(d)(1)(B), (C), (D), (E), (F), and (G). FTA recognizes that a Public Transportation Agency Safety Plan for a large, multi-modal, complex public transportation system most likely will be more complex than that of a very small bus operator. The scalability of SMS will allow transit agencies to develop safety plans that will meet the unique needs of their operating environments. FTA established a minimal set of Safety Assurance requirements for small public transportation providers to minimize their administrative, financial, and regulatory burdens.

In accordance with 49 U.S.C. 5329(d)(1)(E), § 673.11(a)(3) requires that each Public Transportation Agency Safety Plan must include safety performance targets based on the safety performance measures established by FTA in the National Public Transportation Safety Plan. In the National Public Transportation Safety Plan, FTA is adopting four initial safety performance measures: (1) Fatalities, (2) Injuries, (3) Safety Events, and (4) System Reliability. These safety performance measures are intended to reduce safety events, fatalities, and injuries. These measures are broad so that they will be relevant to all public transportation modes, and they are intended to focus transit agencies on the development of specific and measureable targets, as well as the actions each agency would implement to improve their own safety outcomes. Through the SMS process, FTA expects transit agencies to develop their own performance indicators and regularly

monitor the performance of their systems to ensure that they are meeting their targets and improving safety outcomes. FTA expects transit agencies to evaluate their safety performances and determine whether they should change their safety performance targets at least annually when the transit agencies are reviewing and updating their Public Transportation Agency Safety Plans. A State or transit agency must make its safety performance targets available to States and Metropolitan Planning Organizations (MPO) to aid States and MPOs in the selection of their own performance targets.

Pursuant to § 673.11(a)(4), each Public Transportation Agency Safety Plan must address any standards or requirements, as applicable, set forth in FTA's Public Transportation Safety Program and FTA's National Public Transportation Safety Plan.

In accordance with 49 U.S.C. 5329(d)(1)(D), § 673.11(a)(5) requires that each transit agency must establish a process and timeline for conducting an annual review and update of its Public Transportation Agency Safety Plan.

Pursuant to § 673.11(a)(6), each rail transit agency must include, or incorporate by reference, in its Public Transportation Agency Safety Plan an emergency preparedness and response plan. Each emergency preparedness and response plan should address, at a minimum: The assignment of employee responsibilities, as necessary and appropriate, during an emergency; the integration of responses to all hazards, as appropriate; and processes for coordination with Federal, State, regional, and local officials with roles and responsibilities for emergency preparedness and response in the transit agency's service area. FTA understands that a transit agency may have developed an emergency preparedness and response plan that addresses these minimum requirements in accordance with regulations from other Federal and State agencies. Historically, FTA has required rail fixed guideway public transportation systems to have emergency preparedness plans through the former State Safety Oversight rule at 49 CFR 659.19(k). FTA intends to require rail transit systems to continue to implement the twenty-one elements of their SSPPs as required under the former provisions of 49 CFR part 659; FTA has repackaged the elements of SSPPs into the four elements of SMS required in today's rule. FTA is establishing the requirement for emergency preparedness and response plans in today's rule under § 673.11(a)(6), and the elements of SMS

in Subpart C cover remaining requirements. FTA has developed a crosswalk between each of the twentyone elements of system safety program plans and each of the elements of SMS. FTA added this crosswalk to the docket and made the crosswalk available on its website as a guidance document at http://fta.dot.gov/tso.html. Additional, more comprehensive guidance regarding the relationship between SSPPs and PTASPs is forthcoming, and FTA will post that guidance on its website (see https://www.transit.dot.gov/regulationsand-guidance/safety/transit-safetyoversight-tso).

FTA notes that there are safety models that include emergency preparedness as a key element. For example, FAA requires certain air carriers to have emergency preparedness plans. See 14 CFR 5.27. Additionally, FRA recently issued a final System Safety Program rule under 49 CFR part 270 which requires railroads to have emergency preparedness plans (see http://www.fra.dot.gov/eLib/Details/L18294). Recent safety-related events have demonstrated the need for emergency preparedness plans in improving safety outcomes nationally.

In addition to the above general requirements, FTA expects a transit agency to comply with all other applicable Federal, State, and local requirements, laws, regulations, and codes as they may relate to safety.

Pursuant to § 673.11(b), a transit agency may develop one Public Transportation Agency Safety Plan for all modes of transit service, or it may develop separate Public Transportation Agency Safety Plans for each mode of service not subject to safety regulation by another Federal entity. If a transit agency has a safety plan for its commuter rail service, passenger ferry service, or aviation service, then the transit agency may not use that plan for purposes of satisfying 49 CFR part 673; the transit agency must develop a separate Public Transportation Agency Safety Plan consistent with this part.

Pursuant to § 673.11(c), each transit agency must maintain its Public Transportation Agency Safety Plan in accordance with the recordkeeping requirements of Subpart D.

Pursuant to § 673.11(d), each State must draft and certify a Public Transportation Agency Safety Plan on behalf of any small public transportation provider located inside of that particular State. A State is not required to draft a Public Transportation Agency Safety Plan if a small public transportation provider notifies the State that it will draft its own plan. In either instance, the transit agency must

ultimately implement and carry out its

safety plan.

If a State drafts and certifies a Public Transportation Agency Safety Plan on behalf of a transit agency, and the transit agency later opts to draft and certify its own Public Transportation Agency Safety Plan, then the transit agency must notify the State, and the transit agency would have one year from the date of the notification to draft and certify a Public Transportation Agency Safety Plan that is compliant with this part.

Pursuant to § 673.11(e), any rail fixed guideway public transportation system that had an SSPP, in accordance with the former SSO rule at 49 CFR part 659 as of October 1, 2012, may keep that plan in effect until one year after the effective date of this final rule.

Pursuant to § 673.11(f), agencies that operate passenger ferries regulated by USCG or rail fixed guideway public transportation service regulated by FRA are not required to develop safety plans for those modes of service.

673.13 Certification of Compliance

In accordance with 49 U.S.C. 5329(d)(1), § 673.13(a) provides that not later than one year after the effective date of the final rule, each transit agency must certify its compliance with the requirements of this part. For small public transportation providers, a State must certify compliance unless the provider opts to draft and certify its own safety plan. In those cases where a State certifies compliance for a small public transportation provider, this certification also must occur within one year after the effective date of this final rule.

In addition to certification, and consistent with the new SSO rule at 49 CFR part 674, each SSOA must review and approve each Public Transportation Agency Safety Plan for every rail transit system within its jurisdiction. In accordance with 49 U.S.C. 5329(e)(4)(iv), an SSOA must have the authority to review, approve, oversee, and enforce the implementation of the Public Transportation Agency Safety Plans of transit agencies operating rail fixed guideway public transportation systems.

Section 673.13(b) requires that each transit agency or State certify compliance with part 673 on an annual basis.

673.15 Coordination With Metropolitan, Statewide, and Non-Metropolitan Planning Processes

In accordance with 49 U.S.C. 5303(h)(2)(B) and 5304(d)(2)(B), each State and transit agency must make its

safety performance targets available to States and Metropolitan Planning Organizations to aid in the planning process. Section 673.15(b) requires, to the maximum extent practicable, a State or transit agency to coordinate with States and Metropolitan Planning Organizations in the selection of State and MPO safety performance targets.

Subpart C—Safety Management Systems

673.21 General Requirements

This section outlines the SMS elements that each transit agency must establish in its Public Transportation Agency Safety Plan. Under today's final, each transit agency must implement an SMS, and each transit agency should scale the SMS to the size, scope, and complexity of the transit agency's operations. Each transit agency must establish processes and procedures which include the four main pillars of SMS: (1) Safety Management Policy; (2) Safety Risk Management; (3) Safety Assurance; and (4) Safety Promotion. FTA expects that the scope and detail for each activity will vary based on the size and complexity of the system. FTA anticipates that activities, and documentation of those activities, for a small bus transit agency will be substantially less than those of a large multi-modal system. FTA has developed a minimal set of requirements under Safety Assurance for all small public transportation providers. To help clarify SMS development and implementation, FTA is issuing guidance and a safety plan template to the industry concurrent with today's final rule, and FTA designed these documents to accommodate the variance in transit system mode, size, and complexity.

673.23 Safety Management Policy

Pursuant to § 673.23(a), a transit agency must establish the organizational accountabilities and responsibilities necessary for implementing SMS and capture these under the first component of SMS, Safety Management Policy. The success of a transit agency's SMS is dependent upon the commitment of the entire organization and begins with the highest levels of transit agency management. The level of detail for organizational accountabilities and responsibilities should be commensurate with the size and complexity of the transit agency.

The Safety Management Policy statement must contain the transit agency's safety objectives. These objectives should include a broad description of the agency's overarching safety goals, which would be based upon that agency's unique needs.

Pursuant to § 673.23(b), a transit agency must include in its Safety Management Policy statement a process that allows employees to report safety conditions to senior management. This process must provide protections for employees who report safety conditions to senior management and a description of behaviors that are unacceptable and that would not be exempt from disciplinary actions. These procedures are critical for ensuring safety. A reporting program allows employees who identify safety hazards and risks in the day-to-day duties to directly notify senior personnel, without fear of reprisal, so that the hazards and risks can be mitigated or eliminated. NTSB has emphasized the need for transit agencies to have non-punitive employee safety reporting programs,3 and this need was discussed at length in NTSB's Investigative Hearing on the WMATA Smoke and Electrical Arcing Incident in Washington, DC on June 23 and 24, 2015.4

Pursuant to § 673.23(c), the Safety Management Policy statement must be communicated throughout the transit agency, including the Board of Directors (or equivalent authority), and each transit agency must make its Safety Management Policy statement readily available to all of its employees and contractors.

Pursuant to § 673.23(d), each transit agency must establish its accountabilities, responsibilities, and organizational structure necessary to meet its safety objectives, particularly as they relate to the development and management of the transit agency's SMS. The level of detail in this section of the safety plan should be commensurate with the size and complexity of a transit agency's operations. At a minimum, a transit agency must identify an Accountable Executive, a Chief Safety Officer or SMS Executive, and agency leadership, executive management, and key staff who would be responsible for the implementation of a transit agency's safety plan.

³NTSB issued Safety Recommendation R–10/02 for the WMATA Metrorail train collision accident on June 22, 2009, found at: http://www.ntsb.gov/investigations/AccidentReports/Reports/RAR1002.pdf. Through this report, NTSB recommends that "FTA facilitate the development of non-punitive safety reporting programs at all transit agencies [in order] to collect reports from employees in all divisions within their agencies."

⁴See the NTSB's hearing materials at http://www.ntsb.gov/news/events/Pages/2015_WMATAWashington_DC_IHG_Agenda.aspx. and http://dms.ntsb.gov/pubdms/search/document.cfm?docID=432379&docketID=57383&mkey=90596.

673.25 Safety Risk Management

Pursuant to § 673.25(a), each transit agency must establish and implement its process for managing safety risk, including the following three steps: (1) Safety hazard identification, (2) safety risk assessment, and (3) safety risk mitigation, for all elements of its public transportation system, including changes to its public transportation system that may impact safety performance. At a minimum, FTA expects each transit agency to apply its safety risk management process to its existing operations and maintenance procedures, the design of a new public transportation system and other capital projects, changes to its existing public transportation system, new operations of service to the public, new operations or maintenance procedures, organizational changes, and changes to operations or maintenance procedures. Additionally, FTA expects each transit agency to develop measures to ensure that safety principles, requirements, and representatives are included in the transit agency's procurement process.5

Pursuant to § 673.25(b)(1), each transit agency must establish a process for safety hazard identification, including the identification of the sources, both proactive and reactive, for identifying hazards and their associated consequences. Activities for hazard identification could include formalized processes where a transit agency identifies hazards throughout its entire system, logs them into a database, performs risk analyses, and identifies mitigation measures. These activities also could include safety focus groups, reviews of safety reporting trends, and for smaller bus systems, it could mean holding a meeting with a few bus drivers, discussing hazards on the system, deciding which ones pose the greatest risk, and then developing mitigation.

A transit agency must apply its process for safety hazard identification to all elements of its system, including but not limited to its operational activities, system expansions, and state of good repair activities. FTA encourages transit agencies to take into account bicycle and pedestrian safety concerns, along with other factors, as agencies are conducting Safety Risk Management.⁶ A transit agency should consider the results of its asset

condition assessments when performing safety hazard identification activities within its SMS. The results of the condition assessments, and subsequent SMS analysis, will inform a transit agency's determination as to whether an asset meets the state of good repair standards under 49 CFR part 625.

Pursuant to § 673.25(b)(2), each transit agency must include, as a source for safety hazard identification, data and information provided by an oversight

authority and FTA.

Safety hazard identification activities should be commensurate with the size of the transit agency's operations. For example, the number of identified hazards for a small rural bus system may be less than the number of hazards identified for a large multi-modal system.

Pursuant to § 673.25(c), each transit agency must establish procedures for assessing and prioritizing safety risks related to the potential consequences of hazards identified and analyzed in § 673.25(b). Each transit agency must assess safety risks in terms of probability (the likelihood of the hazard producing the potential consequences) and severity (the damage, or the potential consequences of a hazard, that may be caused if the hazard is not eliminated or its consequences are not successfully mitigated).

Pursuant to § 673.25(d), each transit agency also must establish criteria for the development of safety risk mitigations that are necessary based on the results of the agency's safety risk assessments. For example, a transit agency may decide that the criteria for developing safety risk mitigations could be the identification of a safety risk, benefit-cost analysis, a system level change (such as the addition of new technology on a vehicle), a change to operational procedures, or the expansion of service. To further illustrate these examples, a transit agency may color code different levels of safety risk ("red" as high, "yellow" as medium, and "green" as minor) and develop different types of safety risk mitigations to correspond to those levels.

673.27 Safety Assurance

Pursuant to § 673.27(a), each transit agency must develop and implement a process for Safety Assurance. Rail fixed guideway public transportation systems and recipients and subrecipients of Federal financial assistance under 49 U.S.C. Chapter 53 that operate more than one hundred vehicles in peak revenue service must develop processes for (1) safety performance monitoring and measurement, (2) management of

change, and (3) continuous improvement. Small public transportation providers only need to develop a process for safety performance monitoring and measurement. Each transit agency's safety assurance activities should be scaled to the size and complexity of its operations. Through these activities, each transit agency should accurately determine whether it is meeting its safety objectives and safety performance targets, as well as the extent to which it is effectively implementing its SMS. Each transit agency must conduct an annual review of the effectiveness of its safety risk mitigations.

Pursuant to § 673.27(b), each transit agency must identify the data and information that it will collect from its operations, maintenance, and public transportation services so that it may monitor the agency's safety performance as well as the effectiveness of its SMS. Each transit agency must monitor its operations and maintenance protocols and procedures, and any safety risk mitigations, to ensure that it is implementing them as planned.

Each transit agency must investigate safety events (as defined in this final rule) and any reports of non-compliance with applicable regulations, standards, and legal authority. Finally, each transit agency must continually monitor information reported to it through any internal safety reporting programs, including the employee safety reporting

program.

Pursuant to § 673.27(c), rail fixed guideway public transportation systems and recipients and subrecipients that are subject to this rule and operate more than one hundred vehicles in peak revenue service must manage changes in their systems. These transit agencies must develop processes for identifying and assessing changes that may introduce new hazards or impact safety performance. If a transit agency determines that a change might impact safety, then the transit agency would need to evaluate the change using Safety Risk Management activities established under § 673.25. These changes would include changes to operations or maintenance procedures, changes to service, the design and construction of major capital projects (such as New Starts and Small Starts projects and associated certifications), organizational changes, and any other changes to a transit agency's system that may impact safety performance. Each rail transit agency should include a description of the safety certification process that it uses to ensure that safety concerns and hazards are adequately addressed prior to the initiation of passenger operations

 $^{^5\,}See\,FTA's$ former State Safety Oversight rule at 49 CFR 659.19(u).

⁶ The United States Department of Transportation is administering a bicycle and pedestrian safety initiative, and FTA encourages transit agencies to consider that initiative when developing their safety plans (see https://www.transportation.gov/ safer-people-safer-streets).

for News Starts and other major capital projects to extend, rehabilitate, or modify an existing system, or to replace vehicles and equipment.

Pursuant to § 673.27(d), rail fixed guideway public transportation systems and recipients and subrecipients that are subject to this rule and operate more than one hundred vehicles in peak revenue service must regularly assess their safety performance. If a transit agency identifies any deficiencies during a safety performance assessment, then it must develop and carry out, under the direction of the Accountable Executive, a plan to address the identified safety deficiencies. FTA expect each transit agency to conduct a safety performance assessment at least annually, and the safety performance assessment can be completed in conjunction with the annual review and update to its overall safety plan as required by 49 U.S.C. 5329(d)(1)(D) and 49 CFR 673.11(a)(5).

673.29 Safety Promotion

This section requires each transit agency to establish competencies and training for all agency employees directly responsible for safety, and to establish and maintain the means for communicating safety performance and SMS information. Pursuant to § 673.29(a), each transit agency must establish a comprehensive safety training program. Through the safety training program, each transit agency must require each employee, as applicable, to complete training to enable the individual to meet his or her role and responsibilities for safety, and to complete refresher training, as necessary, to stay current with the agency's safety practices and procedures.

Pursuant to § 673.29(b), each transit agency must ensure that all employees are aware of any policies, activities, and procedures that are related to their safety-related roles and responsibilities. Safety communications may include information on hazards and safety risks that are relevant to the employee's role and responsibilities; explain reasons that a transit agency introduces or changes policies, activities, or procedures; and explain to an employee when actions are taken in response to reports submitted by the employee through the employee safety reporting program. FTA expects that each transit agency would define the means and mechanisms for effective safety communication based on its organization, structure, and size of operations.

Subpart D—Safety Plan Documentation and Recordkeeping

673.31 Safety Plan Documentation

This section requires each transit agency to keep records of its documents that are developed in accordance with this part. FTA expects a transit agency to maintain documents that set forth its Public Transportation Agency Safety Plan, including those related to the implementation of its SMS such as the results from SMS processes and activities. For the purpose of reviews, investigations, audits, or other purposes, this section requires each transit agency to make these documents available to FTA, SSOAs in the case of rail transit systems, and other Federal agencies as appropriate. A transit agency must maintain these documents for a minimum of three years.

V. Regulatory Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and USDOT Regulatory Policies and Procedures

Executive Orders 12866 and 13563 direct agencies to propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); tailor its regulations to impose the least burden on society; assess all costs and benefits of available regulatory alternatives; and, if regulation is necessary, to select regulatory approaches that maximizes net benefits—including potential economic, environmental, public health, and safety effects, distributive impacts, and equity. Executive Order 13563 also emphasizes the importance of harmonizing rules and promoting flexibility.

FTA drafted this final rule in accordance with the principles set forth in Executive Orders 12866 and 13563. FTA has determined that this final rule is a significant regulatory action due to significant public interest in the area of transit safety. However, this rule is not estimated to be "economically significant" within the meaning of Executive Order 12866.

As discussed in greater detail below, FTA was able to estimate some, but not all, of the rule's costs. FTA was able to estimate the costs for transit agencies to develop and implement Public Transportation Agency Safety Plans which are approximately \$41 million in the first year, and \$30 million in each subsequent year, with annualized costs of \$31 million discounted at 7 percent. These costs result from developing and

certifying safety plans, documenting the SMS approach, implementing SMS, and associated recordkeeping. FTA was not able to estimate the costs of actions that transit agencies would be required to take to mitigate risk as a result of implementing this rule, such as vehicle modifications, additional training, technology investments, or changes to operating procedures and practices.

FTA has placed in the docket a final Regulatory Impact Analysis (RIA) that analyzes the benefits and costs of the regulatory changes in accordance with Executive Orders 12866 and 13563, and United States Department of Transportation (USDOT) policy.

Through this final rule, FTA requires all operators of public transportation systems that receive Federal financial assistance under 49 U.S.C. Chapter 53 to develop and implement Public Transportation Safety Plans in accordance with 49 U.S.C. 5329, using the SMS approach. As discussed above, FTA is deferring regulatory action at this time regarding recipients of FTA financial assistance under 49 U.S.C. 5310 and/or 49 U.S.C. 5311.

SMS is a flexible, scalable approach to safety that has been widely adopted across multiple modes of transportation in both the public and private sectors and overlaps significantly with the requirements included in 49 U.S.C. 5329. It employs a systematic, datadriven approach in which risks to safety are identified, then controlled or mitigated to acceptable levels. SMS brings business-like methods and principles to safety, similar to the ways in which an organization manages its finances, through safety plans, with targets and performance indicators, and continuous monitoring of safety performance throughout an organization.

In addition to responding to the specific statutory mandate, this final rule responds to National Transportation Safety Board (NTSB) recommendations regarding an expansion of SMS to reduce the risks of transit crashes. From 2004 to 2016, NTSB reported on eleven transit accidents that, collectively, resulted in 16 fatalities, 386 injuries, and over \$30 million in property damages. Although transit systems have historically been among the safest means of surface transportation, the transit industry is facing increased pressures at a time when ridership has grown, infrastructure is aging, and large numbers of the workforce are retiring. During that same 2004-2016 time period, transit agencies reported over 290,000 incidents and other events,

more than 2,600 fatalities, and over 301,000 injuries to the NTD.

This RIA provides quantitative estimates of the expected compliance costs associated with the rule. Costs for transit agencies were estimated based on the staff labor hours, information technology systems, and travel costs associated with implementing the requirements of the proposed rule, with adjustments for agency size and for agencies' existing level of maturity with SMS approaches. FTA estimated three main cost areas: (1) Developing and certifying safety plans; (2) implementing and documenting the SMS approach; and (3) associated recordkeeping. Staff time was monetized using data on wage rates and benefits in the transit industry. Over the 20-year analysis period, total costs are estimated at \$324 million in present value (using a 7% discount rate), or the equivalent of \$31 million per year.

As previously noted, FTA was unable to estimate the cost of actions that agencies would take to mitigate or eliminate safety problems identified through implementation of their safety plans. FTA is unaware of information sources or methods to predict with sufficient confidence the number or type of safety problems agencies will identify through implementation of their safety plans, or the number, type, and cost of actions that agencies will take to address such problems. For similar reasons, FTA also is unable to quantify the rule's benefits. FTA sought information from the public through the NPRM for this rulemaking that would assist FTA with analyzing the benefits and costs of actions by agencies to mitigate or eliminate safety problems such as the number, types, benefits, and costs of such actions, but FTA did not receive adequate data from the public to assist with this effort.

FTA calculated potential safety benefits that could be realized by bus and rail modes if safety management practices outlined in the rule are followed to identify and implement investment strategies to reduce safety risk. FTA monetized benefits using information on transit crash costs, including direct costs and USDOT-standard statistical values for fatality and injury prevention. Although many other sectors report reductions in safety incidents after adopting SMS, it is not possible to transfer that experience to the transit industry due to the differences in organizational structures and practices.

FTA was unable to quantify the rule's benefits. To estimate safety benefits, one would need information regarding the causes of safety events and the factors that may cause future events. This information is generally unavailable in the public transportation sector, given the infrequency and diversity of the type of safety events that occur. In addition, one would need information about the safety problems that agencies are likely to find through implementation of their safety plans and the actions agencies are likely to take to address those problems. Instead of quantifying benefits, FTA estimated the potential safety benefits if additional unquantified mitigation investments occur. The potential safety benefits are an estimate of the cost of bus and rail safety events over a future 20-year period. FTA extrapolated the estimate based on the cost of bus and rail incidents that occurred from 2010 to 2016, assuming no growth in the number of incidents in the future.

The benefits of SMS primarily will result from mitigating actions. As previously stated, FTA could not account for the benefits and costs of such actions in this analysis. FTA has not estimated the benefits of implementing SMS without mitigating actions, but expects such benefits are unlikely to be large. Estimated costs for the Public Transportation Agency Safety Plans include certain activities that likely will yield safety improvements, such as improved communication, identification of hazards, and greater employee awareness. It is plausible that these changes alone could produce reductions in safety events that surpass estimated costs.

Under the performance management framework established by MAP–21, States, MPOs, and transit providers must establish targets in key national performance areas to document expectations for future performance. Pursuant to 49 U.S.C. 5303(h)(2)(B)(ii) and 5304(d)(2)(B)(iii), States and MPOs must coordinate the selection of their performance targets, to the maximum extent practicable, with performance targets set by transit providers under 49 U.S.C. 5326 (transit asset management) and 49 U.S.C. 5329 (safety), to ensure consistency.

In the joint FTA and FHWA Planning Rule, both agencies indicate that their performance-related rules would implement the basic elements of a performance management framework, including the establishment of measures and associated target setting. Because the performance-related rules implement these elements and the difficulty in estimating costs of target setting associated with unknown measures, the joint FTA and FHWA Planning Rule did not assess these costs. Rather, FTA and FHWA proposed that the costs associated with target setting at every level would be captured in each agency's respective "performance management" rules. For example, in its second performance management rule NPRM, FHWA assumes that the incremental costs to States and MPOs for establishing performance targets reflect the incremental wage costs for an operations manager and a statistician to analyze performance-related data.

The RIA accompanying the joint FTA and FHWA Planning Rule captures the costs of the effort by States, MPOs, and transit providers to coordinate in the setting of State and MPO transit performance targets for state of good repair and safety. FTA believes that the cost to MPOs and States to set transit performance targets is included within the costs of coordination. FTA requested comments on this issue through this rulemaking, and it received none.

A summary of the potential benefits and costs of this rule is provided in Table 2 below.

TABLE 2—SUMMARY OF THE COSTS AND THE POTENTIAL BENEFITS IF ADDITIONAL UNQUANTIFIED MITIGATION INVESTMENTS OCCUR

| | Current dollar value | 7% Discounted value | 3% Discounted value |
|-------------------------------|--|--|--|
| Bus Events (20-Year Estimate) | \$78,698,984,508 45,019,196,393 123,718,180,901 | \$38,413,831,624 21,974,360,164 60,388,191,787 | \$56,680,780,091 32,423,838,587 89,104,618,678 |
| Qualitative Benefits | Reduced safety incidentReduced delays in oper | s with mitigation actions. ations. | |

TABLE 2—SUMMARY OF THE COSTS AND THE POTENTIAL BENEFITS IF ADDITIONAL UNQUANTIFIED MITIGATION INVESTMENTS OCCUR—Continued

| | Current dollar value | 7% Discounted value | 3% Discounted value |
|------------------------------------|---|---------------------|---------------------|
| Estimated Costs (20-Year Estimate) | 602,485,710 | 323,732,747 | 450,749,898 |
| Unquantified Costs | • Investments associated with mitigating safety risks (such as additional training, vehicle modification, operational changes, maintenance, and information dissemination). | | |
| Estimated Cost (Annualized) | | 30,558,081 | 30,297,473 |

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order 13771 applies to any action considered "significant" under Executive Order 12866 that imposes total costs greater than zero. Actions subject to Executive Order 13771 must be offset by the elimination of existing costs associated with at least two prior regulations. This final rule is an action under Executive Order 13771 because it is considered a "significant regulatory action" under Executive Order 12866.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), FTA has evaluated the effects of this rule on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities.

The rule will affect approximately 625 small entities, most of which are small government entities and small nonprofit organizations that operate public transportation systems in smallurbanized areas. Compliance costs will vary according to agency size and complexity, the extent of current SMS practices, and the extent of current asset management practices. Costs are illustrated by an example calculation for a small operator (less than one hundred non-rail vehicles in maximum revenue service) of a public transportation system that receives Formula Grants for Urbanized Areas under 49 U.S.C. 5307, for which compliance costs are approximately \$20,600 per agency (this estimate excludes the cost of mitigating actions). For the sake of comparison, while transit agency operations budgets vary significantly, the average for small Section 5307 agencies is around \$6.3 million per year. Thus, the estimated costs of the rule are around 0.3% of agency budgets for small Section 5307 agencies. FTA is minimizing the costs for smaller operators of public transportation systems by requiring the States in which they are located to draft and certify Public Transportation Agency Safety Plans on their behalf,

unless the operator chooses to develop and certify its own plan. Additionally, to lower the costs for smaller operators of public transportation systems, FTA is adopting the SMS approach to safety, which is scalable for the specific needs of a particular transit agency. To further reduce the burdens of this final rule, FTA tailored it by eliminating a series of Safety Assurance requirements specifically for small public transportation providers. As discussed in other sections of this document, small public transportation providers only need to develop Safety Assurance procedures for performance monitoring and measurement; they would not need to develop Safety Assurances procedures for management of change and continuous improvement. FTA also eliminated certain Safety Assurance and recordkeeping requirements for all transit operators, including small public transportation providers, to minimize the rule's costs. Concurrent with today's final rule, FTA is issuing a safety plan template with instructions and considerations to assist transit agencies with the development of their plans and to help reduce the overall costs associated with that effort.

Overall, while the rule may affect a substantial number of small entities, these impacts would not be significant due to the low magnitude of the costs. Moreover, FTA has designed the rule to allow flexibility for small entities. FTA is providing additional analysis of the Regulatory Flexibility Act's application to this rule in Regulatory Impact Analysis posted to the docket.

Unfunded Mandates Reform Act of 1995

This 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; codified at 2 U.S.C. 1501 *et seq.*).

Pursuant to 2 U.S.C. 1501(8), one of the purposes of the Unfunded Mandates Reform Act is to consider "the effect of . . . Federal statutes and regulations that impose Federal intergovernmental mandates." The term "Federal intergovernmental mandate" is defined at 2 U.S.C. 658(5)(A)(i) to mean "any provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, except . . . a condition of Federal assistance."

Given the fact that FTA's authorizing statute at 49 U.S.C. 5329(d) makes the development and implementation of Public Transportation Agency Safety Plans a condition of FTA Federal financial assistance, and given that FTA is proposing to require transit agencies to annually certify that they have safety plans consistent with this rule as a condition of that Federal financial assistance, this rule will not impose unfunded mandates.

Executive Order 13132 (Federalism)

This final rule has been analyzed in accordance with the principles and criteria established by Executive Order 13132, and FTA has determined that this rule will not have sufficient Federalism implications to warrant the preparation of a Federalism assessment. FTA has also determined that this rule will not preempt any State law or State regulation or affect the States' abilities to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations effectuating Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this rule.

Paperwork Reduction Act (PRA)

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. et seq.) (PRA), and the White House Office of Management and Budget's (OMB) implementing regulation at 5 CFR 1320.8(d), FTA is seeking approval from OMB for the Information Collection Request abstracted below. FTA acknowledges that this rule entails the collection of information to implement the Public Transportation Agency Safety Plan requirements of 49 U.S.C. 5329(d). Specifically, an operator of a public

transportation system must do the following: (1) Develop and certify a Public Transportation Agency Safety Plan; (2) implement and document the SMS approach; and (3) associated recordkeeping. As discussed above, FTA is deferring regulatory action at this time regarding recipients of FTA financial assistance under 49 U.S.C. 5310 and/or 49 U.S.C. 5311.

FTA sought public comments to evaluate whether the proposed collection of information is necessary for the proper performance of FTA's functions, including whether the information will have practical utility; whether the estimation of the burden of the proposed information collection is accurate, including the validity of the methodologies and assumptions used; ways in which the quality, utility, and clarity of the information can be enhanced; and whether the burden can be minimized, including through the use of automated collection techniques or other forms of information technology. FTA received no public comments on these issues.

Readers should note that the information collection would be specific to each operator of a public transportation system in an effort to facilitate and record the operator's safety responsibilities and activities. The paperwork burden for each operator

of a public transportation system will be proportionate to the size and complexity of its operations. For example, an operator of a rail fixed guideway system and a bus system may need to generate more documentation than an operator of a bus system only.

Also, readers should note that FTA has required rail fixed guideway public transportation systems to develop System Safety Program Plans and System Security Plans in accordance with the former regulatory requirements at 49 CFR part 659. FTA has collected information from States and State Safety Oversight Agencies regarding these plans, and FTA anticipates that operators of rail fixed guideway systems will utilize some of this documentation for purposes of developing Public Transportation Agency Safety Plans. Please see FTA's currently approved collection, 2132-0558, available at http://www.reginfo.gov/public/do/ PRAMain.

Type of Collection: Operators of public transportation systems.

Type of Review: OMB Clearance. New

Information Collection Request.

Summary of the Collection: The information collection includes (1) The development and certification of a Public Transportation Agency Safety Plan; (2) the implementation and documentation of the SMS approach;

Need for and Expected Use of the Information to be Collected: Collection of information for this program is necessary to ensure that operators of public transportation systems are performing their safety responsibilities and activities required by law at 49 U.S.C. 5329(d). Without the creation of Public Transportation Agency Safety Plans, FTA would be unable to determine each State's compliance with 49 U.S.C. 5329(d).

Respondents: Respondents include operators of public transportation as defined under 49 U.S.C. 5302(14). FTA is deferring regulatory action at this time on recipients of FTA financial assistance under 49 U.S.C. 5310 and/or 49 U.S.C. 5311. The total number of respondents is 336. This figure includes 242 respondents that are States, direct recipients, rail fixed guideway systems that receive Urbanized Area Formula Program funds under 49 U.S.C. 5307, or large bus systems that receive Urbanized Area Formula Program funds under 49 U.S.C. 5307. This figure also includes 94 respondents that receive Urbanized Area Formula Program funds under 49 U.S.C. 5307, operate one hundred or fewer vehicles in revenue service, and do not operate rail fixed guideway service that may draft and certify their own safety plans.

Frequency: Annual.

ESTIMATED TOTAL ANNUAL BURDEN HOURS ON RESPONDENTS

and (3) associated recordkeeping.

| | Total responses | Burden hours per response | Total annual burden |
|---------------------------|-----------------|------------------------------|---------------------|
| Rail: | | | _ |
| Development/Certification | 60 | 48 | 2,862 |
| Development/Certification | 60 | 1,114 | 66,869 |
| Recordkeeping | 60 | 43 | 2,562 |
| Large 5307: | | | |
| Development/Certification | 127 | 48 | 6,123 |
| Development/Certification | 127 | 760 | 96,581 |
| Recordkeeping | 127 | 42 | 5,298 |
| Small 5307: | | | |
| Development/Certification | 94 | 19 | 1,773 |
| Implement/Document | 625 | 270 | 168,622 |
| Recordkeeping | 625 | 38 | 23,647 |
| States/Direct Recipients: | | | |
| Development/Certification | 55 | 40 | 2,206 |
| Implement/Document | 55 | 0 | 0 |
| Recordkeeping | 55 | 0 | 0 |
| Grand Total | 336 | 2,422 | 376,543 |

FTA calculated costs using the same methodology that it used for the Regulatory Impact Analysis. FTA summarized the PRA costs in the table below. The total PRA cost of the rule is approximately \$33 million per year averaged over the first three years, which is an average of \$98,791 per respondent per year, or \$38,256 per response per year.

| PRA costs | Year 1 | Year 2 | Year 3 | Total |
|---------------------------------|-----------|----------|----------|-----------|
| Rail: Development/Certification | \$733,863 | \$86,858 | \$86,858 | \$907,579 |

| PRA costs | Year 1 | Year 2 | Year 3 | Total |
|---------------------------|------------|-----------|-----------|------------|
| Implement/Document | 9,366,439 | 6,651,817 | 6,651,817 | 22,670,072 |
| Recordkeeping | 1,179,917 | 1,179,917 | 1,179,917 | 3,539,750 |
| Large 5307: | | | | |
| Development/Certification | 1,624,085 | 137,866 | 137,866 | 1,899,818 |
| Implement/Document | 9,235,788 | 6,593,697 | 6,593,697 | 22,423,182 |
| Recordkeeping | 1,830,066 | 1,830,066 | 1,830,066 | 5,490,199 |
| Small 5307: | | | | |
| Development/Certification | 436,058 | 48,929 | 48,929 | 533,917 |
| Implement/Document | 12,166,099 | 9,118,251 | 9,118,251 | 30,402,601 |
| Recordkeeping | 3,565,974 | 3,565,974 | 3,565,974 | 10,697,922 |
| States/Direct Recipients: | | | | |
| Development/Certification | 425,782 | 20,045 | 20,045 | 465,871 |
| Implement/Document | 0 | 0 | 0 | 0 |
| Recordkeeping | 183,333 | 183,333 | 183,333 | 550,000 |

National Environmental Policy Act

The National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.), requires Federal agencies to analyze the potential environmental effects of their proposed actions either through a Categorical Exclusion, an Environmental Assessment, or an Environmental Impact Statement. This rule is categorically excluded under FTA's NEPA implementing regulations at 23 CFR 771.118(c)(4), which covers planning and administrative activities that do not involve or lead directly to construction, such as the promulgation of rules, regulations, directives, and program guidance. FTA has determined that no unusual circumstances exist and that this Categorical Exclusion is applicable.

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

Executive Order 12898 directs every Federal agency to make environmental justice part of its mission by identifying and addressing the effects of all programs, policies, and activities on minority populations and low-income populations. The DOT's environmental justice initiatives accomplish this goal by involving the potentially affected public in developing transportation projects that fit harmoniously within their communities without sacrificing safety or mobility. FTA has developed a program circular addressing environmental justice in transit projects, Circular 4703.1, Environmental Justice Policy Guidance for Federal Transit Administration Recipients. The Circular is designed to provide a framework to assist recipients as they integrate principles of environmental justice into their transit decision-making process. The Circular contains recommendations for State DOTs, MPOs, and transit providers on (1) how to fully engage environmental justice populations in

the transportation decision-making process; (2) how to determine whether environmental justice populations would be subjected to disproportionately high and adverse human health or environmental effects of a public transportation project, policy, or activity; and (3) how to avoid, minimize, or mitigate these effects. This rule will not cause adverse environmental impacts, and as a result, minority populations and low-income populations will not be disproportionately impacted.

Executive Order 12630 (Taking of Private Property)

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Executive Order 12988 (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.

Executive Order 13045 (Protection of Children)

FTA has analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. FTA certifies that this rule will not cause an environmental risk to health or safety that may disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

FTA has analyzed this rule under Executive Order 13175 (Nov. 6, 2000), and has determined that it 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 laws. Therefore, a tribal summary impact statement is not required.

Notwithstanding the above, FTA notes that it conducted extensive outreach with tribes throughout this rulemaking. Specifically, on February 12, 2016, FTA conducted public outreach for tribes and hosted a Tribal Technical Assistance Workshop wherein FTA presented its proposed rule and responded to numerous technical questions from tribes. FTA subsequently delivered the same presentation during a webinar series open to all members of the public on February 24, March 1, March 2, and March 3. On March 7, FTA delivered the same presentation at an outreach session hosted by the National Rural Transit Assistance Program, which also was open to all members of the public. During each of these public outreach sessions and the public webinar series, FTA received and responded to numerous technical questions regarding the NPRM. FTA recorded the presentations, including the question and answer sessions, and made available the following documents on the public docket for this rulemaking (Docket FTA-2015-0021): (1) FTA's PowerPoint Presentation from the public outreach sessions and public webinar series (https:// www.regulations.gov/document?D=FTA-2015-0021-0012); (2) a written transcript of FTA's public webinar of March 1, 2016 (https://www.regulations.gov/ document?D=FTA-2015-0021-0010); (3) a consolidated list of every Question and FTA Answer from the public outreach sessions and public webinar series (https://www.regulations.gov/ document?D=FTA-2015-0021-0041); and (4) the results of polling questions from FTA's public outreach sessions (https://www.regulations.gov/ document?D=FTA-2015-0021-0011). FTA also uploaded onto YouTube an audiovisual recording of its webinar

from March 1, 2016. The video is available at the following link: https://www.youtube.com/watch?v=FBj5HRatwGA&feature=youtu.be.

FTA also notes that, in advance of publishing an NPRM, FTA sought comment from the transit industry, including tribes, on a wide range of topics pertaining to safety and asset management through an ANPRM. In the NPRM, FTA asked specific questions about how today's rule should apply to tribal recipients and subrecipients of Section 5311 funds.

In light of the comments that FTA received from tribes in response to the NPRM, and in an effort to further reduce the burdens of this final rule, FTA is deferring regulatory action regarding the applicability of this rule to operators of public transportation systems that only receive Section 5310 and/or Section 5311 funds, including tribal transit operators. FTA is deferring action pending further evaluation of information and safety data to determine the appropriate level of regulatory burden necessary to address the safety risk presented by these operators.

Executive Order 13211 (Energy Effects)

FTA has analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). FTA has determined that this rule is not a significant energy action under that Executive Order because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Privacy Act

Any individual is able to search the electronic form of all comments received on any FTA docket by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, or other entity). You may review USDOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477).

Statutory/Legal Authority for This Rulemaking

FTA is issuing this final rule under the authority of section 20021 of MAP—21, which requires public transportation agencies to develop and implement comprehensive safety plans. This authority was reauthorized under the FAST Act. The authority is codified at 49 U.S.C. 5329(d).

Regulation Identification Number

A 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 set forth in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 673

Mass transportation, Safety.

K. Jane Williams,

Acting Administrator.

■ For the reasons set forth in the preamble, and under the authority of 49 U.S.C. 5329(d) and 5334, and the delegations of authority at 49 CFR 1.91, FTA hereby amends Chapter VI of Title 49, Code of Federal Regulations by adding part 673 to read as follows:

PART 673—PUBLIC TRANSPORTATION AGENCY SAFETY PLANS

Subpart A—General

673.1 Applicability.

673.3 Policy.

673.5 Definitions.

Subpart B—Safety Plans

673.11 General requirements.

673.13 Certification of compliance.

673.15 Coordination with metropolitan, statewide, and non-metropolitan planning processes.

Subpart C—Safety Management Systems

673.21 General requirements.

673.23 Safety management policy.

673.25 Safety risk management.

673.27 Safety assurance.

673.29 Safety promotion.

Subpart D—Safety Plan Documentation and Recordkeeping

673.31 Safety plan documentation.

Authority: 49 U.S.C. 5329(d) and 5334; 49 CFR 1.91.

Subpart A—General

§ 673.1 Applicability.

(a) This part applies to any State, local governmental authority, and any other operator of a public transportation system that receives Federal financial assistance under 49 U.S.C. Chapter 53.

(b) This part does not apply to an operator of a public transportation system that only receives Federal financial assistance under 49 U.S.C. 5310, 49 U.S.C. 5311, or both 49 U.S.C. 5310 and 49 U.S.C. 5311.

§ 673.3 Policy.

The Federal Transit Administration (FTA) has adopted the principles and

methods of Safety Management Systems (SMS) as the basis for enhancing the safety of public transportation in the United States. FTA will follow the principles and methods of SMS in its development of rules, regulations, policies, guidance, best practices, and technical assistance administered under the authority of 49 U.S.C. 5329. This part sets standards for the Public Transportation Agency Safety Plan, which will be responsive to FTA's Public Transportation Safety Program, and reflect the specific safety objectives, standards, and priorities of each transit agency. Each Public Transportation Agency Safety Plan will incorporate SMS principles and methods tailored to the size, complexity, and scope of the public transportation system and the environment in which it operates.

§ 673.5 Definitions.

As used in this part:

Accident means an Event that involves any of the following: A loss of life; a report of a serious injury to a person; a collision of public transportation vehicles; a runaway train; an evacuation for life safety reasons; or any derailment of a rail transit vehicle, at any location, at any time, whatever the cause.

Accountable Executive means a single, identifiable person who has ultimate responsibility for carrying out the Public Transportation Agency Safety Plan of a public transportation agency; responsibility for carrying out the agency's Transit Asset Management Plan; and control or direction over the human and capital resources needed to develop and maintain both the agency's Public Transportation Agency Safety Plan, in accordance with 49 U.S.C. 5329(d), and the agency's Transit Asset Management Plan in accordance with 49 U.S.C. 5326.

Chief Safety Officer means an adequately trained individual who has responsibility for safety and reports directly to a transit agency's chief executive officer, general manager, president, or equivalent officer. A Chief Safety Officer may not serve in other operational or maintenance capacities, unless the Chief Safety Officer is employed by a transit agency that is a small public transportation provider as defined in this part, or a public transportation provider that does not operate a rail fixed guideway public transportation system.

Equivalent Authority means an entity that carries out duties similar to that of a Board of Directors, for a recipient or subrecipient of FTA funds under 49 U.S.C. Chapter 53, including sufficient authority to review and approve a recipient or subrecipient's Public Transportation Agency Safety Plan.

Event means any Accident, Incident, or Occurrence.

FTA means the Federal Transit Administration, an operating administration within the United States Department of Transportation.

Hazard means any real or potential condition that can cause injury, illness, or death; damage to or loss of the facilities, equipment, rolling stock, or infrastructure of a public transportation system; or damage to the environment.

Incident means an event that involves any of the following: A personal injury that is not a serious injury; one or more injuries requiring medical transport; or damage to facilities, equipment, rolling stock, or infrastructure that disrupts the operations of a transit agency.

Investigation means the process of determining the causal and contributing factors of an accident, incident, or hazard, for the purpose of preventing recurrence and mitigating risk.

National Public Transportation Safety Plan means the plan to improve the safety of all public transportation systems that receive Federal financial assistance under 49 U.S.C. Chapter 53.

Occurrence means an Event without any personal injury in which any damage to facilities, equipment, rolling stock, or infrastructure does not disrupt the operations of a transit agency.

Operator of a public transportation system means a provider of public transportation as defined under 49 U.S.C. 5302(14).

Performance measure means an expression based on a quantifiable indicator of performance or condition that is used to establish targets and to assess progress toward meeting the established targets.

Performance target means a quantifiable level of performance or condition, expressed as a value for the measure, to be achieved within a time period required by the Federal Transit Administration (FTA).

Public Transportation Agency Safety Plan means the documented comprehensive agency safety plan for a transit agency that is required by 49 U.S.C. 5329 and this part.

Rail fixed guideway public transportation system means any fixed guideway system that uses rail, is operated for public transportation, is within the jurisdiction of a State, and is not subject to the jurisdiction of the Federal Railroad Administration, or any such system in engineering or construction. Rail fixed guideway public transportation systems include but are not limited to rapid rail, heavy rail, light rail, monorail, trolley,

inclined plane, funicular, and automated guideway.

Rail transit agency means any entity that provides services on a rail fixed guideway public transportation system.

Risk means the composite of predicted severity and likelihood of the potential effect of a hazard.

Risk mitigation means a method or methods to eliminate or reduce the effects of hazards.

Safety Assurance means processes within a transit agency's Safety Management System that functions to ensure the implementation and effectiveness of safety risk mitigation, and to ensure that the transit agency meets or exceeds its safety objectives through the collection, analysis, and assessment of information.

Safety Management Policy means a transit agency's documented commitment to safety, which defines the transit agency's safety objectives and the accountabilities and responsibilities of its employees in regard to safety.

Safety Management System (SMS) means the formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of a transit agency's safety risk mitigation. SMS includes systematic procedures, practices, and policies for managing risks and hazards.

Safety Management System (SMS) Executive means a Chief Safety Officer or an equivalent.

Safety performance target means a Performance Target related to safety management activities.

Safety Promotion means a combination of training and communication of safety information to support SMS as applied to the transit agency's public transportation system.

Safety risk assessment means the formal activity whereby a transit agency determines Safety Risk Management priorities by establishing the significance or value of its safety risks.

Safety Risk Management means a process within a transit agency's Public Transportation Agency Safety Plan for identifying hazards and analyzing, assessing, and mitigating safety risk.

Serious injury means any injury which:

- (1) Requires hospitalization for more than 48 hours, commencing within 7 days from the date of the injury was
- (2) Results in a fracture of any bone (except simple fractures of fingers, toes, or noses);
- (3) Causes severe hemorrhages, nerve, muscle, or tendon damage;
- (4) Involves any internal organ; or(5) Involves second- or third-degree
- (5) Involves second- or third-degree burns, or any burns affecting more than 5 percent of the body surface.

Small public transportation provider means a recipient or subrecipient of Federal financial assistance under 49 U.S.C. 5307 that has one hundred (100) or fewer vehicles in peak revenue service and does not operate a rail fixed guideway public transportation system.

State means a State of the United States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, and the Virgin Islands.

State of good repair means the condition in which a capital asset is able to operate at a full level of performance.

State Safety Oversight Agency means an agency established by a State that meets the requirements and performs the functions specified by 49 U.S.C. 5329(e) and the regulations set forth in 49 CFR part 674.

Transit agency means an operator of a public transportation system.

Transit Asset Management Plan means the strategic and systematic practice of procuring, operating, inspecting, maintaining, rehabilitating, and replacing transit capital assets to manage their performance, risks, and costs over their life cycles, for the purpose of providing safe, cost-effective, and reliable public transportation, as required by 49 U.S.C. 5326 and 49 CFR part 625.

Subpart B—Safety Plans

§ 673.11 General requirements.

- (a) A transit agency must, within one calendar year after July 19, 2019, establish a Public Transportation Agency Safety Plan that meets the requirements of this part and, at a minimum, consists of the following elements:
- (1) The Public Transportation Agency Safety Plan, and subsequent updates, must be signed by the Accountable Executive and approved by the agency's Board of Directors, or an Equivalent Authority.
- (2) The Public Transportation Agency Safety Plan must document the processes and activities related to Safety Management System (SMS) implementation, as required under subpart C of this part.

(3) The Public Transportation Agency Safety Plan must include performance targets based on the safety performance measures established under the National Public Transportation Safety Plan.

(4) The Public Transportation Agency Safety Plan must address all applicable requirements and standards as set forth in FTA's Public Transportation Safety Program and the National Public Transportation Safety Plan. Compliance with the minimum safety performance standards authorized under 49 U.S.C. 5329(b)(2)(C) is not required until standards have been established through the public notice and comment process.

(5) Each transit agency must establish a process and timeline for conducting an annual review and update of the Public Transportation Agency Safety Plan.

(6) A rail transit agency must include or incorporate by reference in its Public Transportation Agency Safety Plan an emergency preparedness and response plan or procedures that addresses, at a minimum, the assignment of employee responsibilities during an emergency; and coordination with Federal, State, regional, and local officials with roles and responsibilities for emergency preparedness and response in the transit agency's service area.

(b) A transit agency may develop one Public Transportation Agency Safety Plan for all modes of service, or may develop a Public Transportation Agency Safety Plan for each mode of service not subject to safety regulation by another

Federal entity.

(c) A transit agency must maintain its Public Transportation Agency Safety Plan in accordance with the recordkeeping requirements in subpart

D of this part.

- (d) A State must draft and certify a Public Transportation Agency Safety Plan on behalf of any small public transportation provider that is located in that State. A State is not required to draft a Public Transportation Agency Safety Plan for a small public transportation provider if that agency notifies the State that it will draft its own plan. In each instance, the transit agency must carry out the plan. If a State drafts and certifies a Public Transportation Agency Safety Plan on behalf of a transit agency, and the transit agency later opts to draft and certify its own Public Transportation Agency Safety Plan, then the transit agency must notify the State. The transit agency has one year from the date of the notification to draft and certify a Public Transportation Agency Safety Plan that is compliant with this part. The Public Transportation Agency Safety Plan drafted by the State will remain in effect until the transit agency drafts its own Public Transportation Agency Safety
- (e) Any rail fixed guideway public transportation system that had a System Safety Program Plan compliant with 49 CFR part 659 as of October 1, 2012, may keep that plan in effect until one year after July 19, 2019.
- (f) Agencies that operate passenger ferries regulated by the United States

Coast Guard (USCG) or rail fixed guideway public transportation service regulated by the Federal Railroad Administration (FRA) are not required to develop agency safety plans for those modes of service.

§ 673.13 Certification of compliance.

(a) Each transit agency, or State as authorized in § 673.11(d), must certify that it has established a Public Transportation Agency Safety Plan meeting the requirements of this part one year after July 19, 2019. A State Safety Oversight Agency must review and approve a Public Transportation Agency Safety Plan developed by rail fixed guideway system, as authorized in 49 U.S.C. 5329(e) and its implementing regulations at 49 CFR part 674.

(b) On an annual basis, a transit agency, direct recipient, or State must certify its compliance with this part.

§ 673.15 Coordination with metropolitan, statewide, and non-metropolitan planning processes.

(a) A State or transit agency must make its safety performance targets available to States and Metropolitan Planning Organizations to aid in the planning process.

(b) To the maximum extent practicable, a State or transit agency must coordinate with States and Metropolitan Planning Organizations in the selection of State and MPO safety

performance targets.

Subpart C—Safety Management Systems

§ 673.21 General requirements.

Each transit agency must establish and implement a Safety Management System under this part. A transit agency Safety Management System must be appropriately scaled to the size, scope and complexity of the transit agency and include the following elements:

(a) Safety Management Policy as described in § 673.23;

(b) Safety Risk Management as described in § 673.25;

(c) Safety Assurance as described in § 673.27; and

(d) Safety Promotion as described in § 673.29.

§ 673.23 Safety management policy.

- (a) A transit agency must establish its organizational accountabilities and responsibilities and have a written statement of safety management policy that includes the agency's safety objectives.
- (b) A transit agency must establish and implement a process that allows employees to report safety conditions to senior management, protections for

employees who report safety conditions to senior management, and a description of employee behaviors that may result in disciplinary action.

(c) The safety management policy must be communicated throughout the

agency's organization.

(d) The transit agency must establish the necessary authorities, accountabilities, and responsibilities for the management of safety amongst the following individuals within its organization, as they relate to the development and management of the transit agency's Safety Management System (SMS):

(1) Accountable Executive. The transit agency must identify an Accountable Executive. The Accountable Executive is accountable for ensuring that the agency's SMS is effectively implemented, throughout the agency's public transportation system. The Accountable Executive is accountable for ensuring action is taken, as necessary, to address substandard performance in the agency's SMS. The Accountable Executive may delegate specific responsibilities, but the ultimate accountability for the transit agency's safety performance cannot be delegated and always rests with the Accountable Executive.

(2) Chief Safety Officer or Safety
Management System (SMS) Executive.
The Accountable Executive must
designate a Chief Safety Officer or SMS
Executive who has the authority and
responsibility for day-to-day
implementation and operation of an
agency's SMS. The Chief Safety Officer
or SMS Executive must hold a direct
line of reporting to the Accountable
Executive. A transit agency may allow
the Accountable Executive to also serve
as the Chief Safety Officer or SMS
Executive.

(3) Agency leadership and executive management. A transit agency must identify those members of its leadership or executive management, other than an Accountable Executive, Chief Safety Officer, or SMS Executive, who have authorities or responsibilities for day-to-day implementation and operation of an agency's SMS.

(4) Key staff. A transit agency may designate key staff, groups of staff, or committees to support the Accountable Executive, Chief Safety Officer, or SMS Executive in developing, implementing, and operating the agency's SMS.

§ 673.25 Safety risk management.

(a) Safety Risk Management process. A transit agency must develop and implement a Safety Risk Management process for all elements of its public transportation system. The Safety Risk

Management process must be comprised of the following activities: Safety hazard identification, safety risk assessment, and safety risk mitigation.

(b) Safety hazard identification. (1) A transit agency must establish methods or processes to identify hazards and consequences of the hazards.

(2) A transit agency must consider, as a source for hazard identification, data and information provided by an oversight authority and the FTA.

- (c) Safety risk assessment. (1) A transit agency must establish methods or processes to assess the safety risks associated with identified safety hazards.
- (2) A safety risk assessment includes an assessment of the likelihood and severity of the consequences of the hazards, including existing mitigations, and prioritization of the hazards based on the safety risk.
- (d) Safety risk mitigation. A transit agency must establish methods or processes to identify mitigations or strategies necessary as a result of the agency's safety risk assessment to reduce the likelihood and severity of the consequences.

§ 673.27 Safety assurance.

(a) Safety assurance process. A transit agency must develop and implement a safety assurance process, consistent with this subpart. A rail fixed guideway public transportation system, and a recipient or subrecipient of Federal financial assistance under 49 U.S.C. Chapter 53 that operates more than one hundred vehicles in peak revenue service, must include in its safety assurance process each of the requirements in paragraphs (b), (c), and (d) of this section. A small public transportation provider only must

include in its safety assurance process the requirements in paragraph (b) of this section.

(b) Safety performance monitoring and measurement. A transit agency must establish activities to:

(1) Monitor its system for compliance with, and sufficiency of, the agency's procedures for operations and maintenance:

(2) Monitor its operations to identify any safety risk mitigations that may be ineffective, inappropriate, or were not implemented as intended;

(3) Conduct investigations of safety events to identify causal factors; and

(4) Monitor information reported through any internal safety reporting programs.

(c) Management of change. (1) A transit agency must establish a process for identifying and assessing changes that may introduce new hazards or impact the transit agency's safety performance.

(2) If a transit agency determines that a change may impact its safety performance, then the transit agency must evaluate the proposed change through its Safety Risk Management process.

(d) Continuous improvement. (1) A transit agency must establish a process to assess its safety performance.

(2) If a transit agency identifies any deficiencies as part of its safety performance assessment, then the transit agency must develop and carry out, under the direction of the Accountable Executive, a plan to address the identified safety deficiencies.

§ 673.29 Safety promotion.

(a) Competencies and training. A transit agency must establish and implement a comprehensive safety

training program for all agency employees and contractors directly responsible for safety in the agency's public transportation system. The training program must include refresher training, as necessary.

(b) Safety communication. A transit agency must communicate safety and safety performance information throughout the agency's organization that, at a minimum, conveys information on hazards and safety risks relevant to employees' roles and responsibilities and informs employees of safety actions taken in response to reports submitted through an employee safety reporting program.

Subpart D—Safety Plan Documentation and Recordkeeping

§ 673.31 Safety plan documentation.

At all times, a transit agency must maintain documents that set forth its Public Transportation Agency Safety Plan, including those related to the implementation of its Safety Management System (SMS), and results from SMS processes and activities. A transit agency must maintain documents that are included in whole, or by reference, that describe the programs, policies, and procedures that the agency uses to carry out its Public Transportation Agency Safety Plan. These documents must be made available upon request by the Federal Transit Administration or other Federal entity, or a State Safety Oversight Agency having jurisdiction. A transit agency must maintain these documents for a minimum of three years after they are created.

[FR Doc. 2018–15167 Filed 7–18–18; 8:45 am]

Reader Aids

Federal Register

Vol. 83, No. 139

Thursday, July 19, 2018

CUSTOMER SERVICE AND INFORMATION

| Federal Register/Code of Federal Regulations | |
|---|--------------|
| General Information, indexes and other finding aids | 202-741-6000 |
| Laws | 741–6000 |
| Presidential Documents | |
| Executive orders and proclamations | 741-6000 |
| The United States Government Manual | 741–6000 |
| Other Services | |
| Electronic and on-line services (voice) | 741-6020 |
| Privacy Act Compilation | 741-6050 |
| Public Laws Update Service (numbers, dates, etc.) | 741–6043 |

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.fdsys.gov.

Federal Register information and research tools, including Public Inspection List, indexes, and Code of Federal Regulations are located at: www.ofr.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to https://public.govdelivery.com/accounts/ USGPOOFR/subscriber/new, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to http://listserv.gsa.gov/archives/publaws-l.html and select *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

CFR Checklist. Effective January 1, 2009, the CFR Checklist no longer appears in the Federal Register. This information can be found online at http://bookstore.gpo.gov/.

FEDERAL REGISTER PAGES AND DATE, JULY

| 19 | 34021–34468 | 2 | 30831–31036. |
|----|-------------|----|--------------|
| | | 3 | 31037-31324. |
| | | 5 | 31325-31440. |
| | | 6 | 31441-31640. |
| | | 9 | 31641-31840. |
| | | 10 | 31841-32060. |
| | | 11 | 32061-32190. |
| | | 12 | 32191-32562. |
| | | 13 | 32563-32758. |
| | | 16 | 32759-33118. |
| | | 17 | 33119-33794. |
| | | 18 | 33795-34020. |
| | | | |

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.

| 2 CFR | 61530833 |
|------------------------|--|
| _ | Proposed Rules: |
| 18031037 | 4433432 |
| 3 CFR | 248 |
| 3 CFN | |
| Proclamations: | 35133432 |
| 976631641 | 120633312 |
| 976734017 | 124033312 |
| 976834019 | 161031896 |
| Executive Orders: | 175033312 |
| 13519 (Revoked by | 10.050 |
| 13844)33115 | 13 CFR |
| 1384232753 | 12034021 |
| 1384332755 | |
| 1384433115 | 14 CFR |
| Administrative Orders: | 131450 |
| Memorandums: | 2131450 |
| Memorandum of June | 2334022 |
| 4, 201831321 | 2531450, 32759 |
| Presidential | 2631450 |
| Determinations: | 2731450 |
| No. 2018-1 of June 4, | 3431450 |
| 201831323 | |
| | 3931325, 31643, 31646, |
| 5 CFR | 31648, 31650, 31850, 32198, |
| 6 (Amended by EO | 32201, 32203, 32563, 33809, |
| 13843)32755 | 33817, 33821, 34029, 34031, |
| 89032191 | 34034 4331450 |
| 89232191 | |
| 89432191 | 4531450 |
| 263433979 | 6031450 |
| Proposed Rules: | 6131450, 34040 |
| 53131694 | 6331450 |
| 7.050 | 6531450 |
| 7 CFR | 6734040 |
| 5231441 | 7131327, 31653, 31853, |
| 76033795 | 31854, 31855, 31857 7332061 |
| 90531442 | 9131450, 34040 |
| 92932193 | |
| 93031444 | 9730833, 30836, 31450, 32764, 32766 |
| 320131841 | 10731450 |
| 428030831 | |
| Proposed Rules: | 11031450 |
| 35731697, 31702 | 11931450 12034040 |
| 90631471 | |
| 98131473 | 12131450 12531450 |
| 120632215 | |
| 122031477 | 12931450 |
| 8 CFR | 13331450 13531450 |
| | 13731450 |
| 21231447 | |
| Proposed Rules: | 14131450 |
| 10333762 | 14231450 |
| 21433762 | 14531450 |
| 10 CFR | 18331450 |
| | Proposed Rules: |
| 3032759, 33046 | 2532807 |
| 3232759, 33046 | 3331479 |
| 3532759, 33046 | 3931488, 31491, 31493, |
| Proposed Rules: | |
| | 31496, 31499, 31504, 31507, |
| 43131704 | 31496, 31499, 31504, 31507, 31509, 31705, 31911, 32221, |
| | 31496, 31499, 31504, 31507, 31509, 31705, 31911, 32221, 33159, 33162, 33873, 34070, |
| 12 CFR | 31496, 31499, 31504, 31507, 31509, 31705, 31911, 32221, 33159, 33162, 33873, 34070, 34072, 34074 |
| | 31496, 31499, 31504, 31507, 31509, 31705, 31911, 32221, 33159, 33162, 33873, 34070, |

| 16 CFR | 40633826 |
|--------------------------|-----------------------------|
| 80132768 | 191031045 |
| 80232768 | 402232580 |
| 80332768 | Proposed Rules: |
| 111230837 | 191031086 |
| 121132566 | 192634076 |
| 123730837 | 4041A32815 |
| 17.050 | 424532815 |
| 17 CFR | 428132815 |
| 21031992 | 30 CFR |
| 22931992 | Proposed Rules: |
| 23031992 | 7031710 |
| 23233119 | 7131710 |
| 23931992 | 7231710 |
| 24031992 24931992 | 7531710 |
| 27431859 | 9031710 |
| Proposed Rules: | 25031343 |
| 131078 | 32 CFR |
| 7533432 | |
| 25533432 | 70631046 |
| | 76331451 |
| 19 CFR | 33 CFR |
| 1231654 | 10030860, 31047, 31883, |
| 00.055 | 32206, 33121, 33122, 33124, |
| 20 CFR | 33125 |
| 40430849 | 11731048, 31452, 31659, |
| 41630849 | 31886, 34041 |
| 21 CFR | 16530862, 30863, 30865, |
| | 30866, 30869, 30871, 30872, |
| 130332784 | 30875, 30877, 31048, 31050, |
| 130831877 | 31052, 31054, 31055, 31057, |
| Proposed Rules: 10132221 | 31059, 31060, 31062, 31886, |
| 57334076 | 31887, 31889, 31891, 32208, |
| 3/3340/0 | 32582, 32591, 33127, 33842, |
| 22 CFR | 34041, 34042, 34046 |
| 4131451 | Proposed Rules: 10031913 |
| | 11732602 |
| 24 CFR | 16531344, 32604, 33165, |
| 2832790 | 34092 |
| 3032790 | 32832227 |
| 8732790 | |
| 18032790 | 34 CFR |
| 20031038 | 30031306 |
| 33031042 | 60031296 |
| 328232790 | 66831296 |
| 25 CFR | 68534047 |
| 8333825 | Proposed Rules: |
| 8533823 | 20033167 |
| 26 CFR | 36 CFR |
| 132524 | |
| Proposed Rules: | Proposed Rules: 1334094 |
| 133875 | 1304034 |
| 30133165 | 37 CFR |
| | 233129 |
| 28 CFR | Proposed Rules: |
| 032759 | 20132068 |
| 20 CEP | |
| 29 CFR | 38 CFR |
| 40533826 | 332716 |

| 4 | |
|--|---|
| 13 | |
| 17 | 31452 |
| Proposed Rules: | 01711 |
| 17 | 31/11 |
| 39 CFR | |
| 3001 | .31258 |
| 3004 | |
| 3007 | |
| Proposed Rules: | |
| 111 | .31712 |
| 113 | .31713 |
| 305031344, 31346, | 31713, |
| 32069, | 33879 |
| 40 CFR | |
| | 01070 |
| 5231064, 31068, 31328, 31330, 31332, | 31072, |
| 32062, 32064, 32209, | 22211 |
| 32794, 32796, 33132, | 32730 |
| 33844, 33846, | 34050 |
| 6330879, | 32213 |
| 8131334, | |
| 180 | 31893 |
| 30032798, | 33134 |
| Proposed Pulos | |
| Ch. I | .31098 |
| 5231087, 31348, | |
| 31352, 31511, 31513, | 31915. |
| 32606, 33168, 33886, | 33892. |
| 33894. | 34094 |
| 63 | .31939 |
| 8031098, | |
| 00 | 32024 |
| 110 | 32024 |
| | 32024 .32227 |
| 110 | 32024 .32227 .32227 |
| 110 112 | 32024 .32227 .32227 .32227 |
| 110 112 116 117 122 | 32024 .32227 .32227 .32227 .32227 |
| 110 112 116 117 122 230 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 33171, 33186 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 33171, 33186 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 33171, 33186 .32227 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .3186 .32227 .32227 .32227 .30889 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .33171, .3186 .32227 .32227 .30889 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .33171, .32227 .32227 .32227 .32227 .32227 .32227 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .30889 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .30889 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .3089 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .30889 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .30889 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .30889 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |
| 110 | 32024 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32227 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 .32071 |

| 486488 | |
|------------------------------------|---|
| 44 CFR | |
| 5961 | 31337 |
| 5961 | 32956 |
| 47 CFR | |
| 51 | 31659 |
| 5430883, 30884 | , 31458, 33139 |
| 6333140 | 31659 |
| 68 | |
| 7333144 | , 33848 |
| 74 | 33144 |
| Proposed Rules: | 00004 |
| 0 | 30901 |
| 5 | |
| 27 | |
| 51 | |
| 54 | |
| 6133899 | |
| 7330901, 31516 | |
| |), 32233 |
| 7430901 | |
| 7430901 | |
| 7430901 48 CFR | , 34096 |
| 7430901 | , 34096 |
| 7430901 48 CFR | , 34096 |
| 7430901 48 CFR 9903 49 CFR 672 | 33146 |
| 7430901 48 CFR 9903 | 33146 |
| 7430901 48 CFR 9903 | 34096 33146 34053 34418 |
| 7430901 48 CFR 990349 CFR 672673 | 34096 33146 34053 34418 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 |
| 7430901 48 CFR 990349 CFR 672673 | 34096 34053 34418 31944 31944 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 32826 |
| 7430901 48 CFR 9903 | 34096 34146 34418 31944 31944 32826 32805 33848 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 32826 32805 33848 33851 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 32826 33848 33851 , 33148, |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 32826 32805 33848 33851 , 33148, 33870 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 32826 32826 33848 33851 , 33148, 33870 7, 31684 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 32826 33848 33851 , 33148, 33870 7, 31684 , 31460 |
| 7430901 48 CFR 9903 | 34096 34053 34418 31944 31944 32826 33848 33851 , 33148, 33870 7, 31684 0, 31460 32615 |
| 7430901 48 CFR 9903 | 340963409634053344183194431944328263384833851 , 33148, 33870 7, 31684 0, 314603261531517 |
| 7430901 48 CFR 9903 | 340963409634053344183194431944328263384833851 , 33148, 33870 7, 31684 0, 314603261531517 6, 32829 |

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 11, 2018

Public Laws Electronic Notification Service (PENS)

PENS is a free electronic mail notification service of newly

enacted public laws. To subscribe, go to http:// listserv.gsa.gov/archives/ publaws-l.html

Note: This service is strictly for E-mail notification of new laws. The text of laws is not available through this service. PENS cannot respond to specific inquiries sent to this address.