



FEDERAL REGISTER

Vol. 84

Thursday,

No. 35

February 21, 2019

Pages 5335–5582

OFFICE OF THE FEDERAL REGISTER



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Contents

Federal Register

Vol. 84, No. 35

Thursday, February 21, 2019

Agency for Healthcare Research and Quality

NOTICES

Supplemental Evidence and Data Request:
Use of Cardiac Resynchronization Therapy: A Systematic
Review Update, 5438–5439

Agricultural Marketing Service

RULES

Mango Promotion, Research and Information Order;
Amendment to Include Frozen Mangos, 5335–5346

PROPOSED RULES

Mango Promotion, Research and Information Order;
Referendum on Inclusion of Frozen Mangos, 5379–5380

Agriculture Department

See Agricultural Marketing Service

See Animal and Plant Health Inspection Service

See Forest Service

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 5404–5405

Air Force Department

RULES

Delivery of Personnel to United States Civilian Authorities
for Trial, 5354

Sale to the Public, 5353

Visual Information Documentation Program, 5353–5354

Alcohol, Tobacco, Firearms, and Explosives Bureau

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Manufacturers of Ammunition, Records and Supporting
Data of Ammunition Manufactured and Disposed of,
5466
Office of Human Resources and Professional
Development Student and Supervisor Training
Validation Surveys, 5465–5466

Animal and Plant Health Inspection Service

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
Agriculture Select Agent Services; Import and Transport
Permits for Non-Select Materials, 5407–5408
Importation of Baby Corn and Baby Carrots from Zambia,
5406–5407
Importation of Citrus from Peru, 5408–5409
Importation of *Phalaenopsis* spp. Plants for Planting in
Approved Growing Media from China into the
Continental United States, 5406
Importation of Swine Hides, Bird Trophies, and Deer
Hides, 5411–5412
Location of Irradiation Treatment Facilities in the United
States, 5409–5410
Environmental Assessments; Availability, etc.:
Field Testing of a Vaccine for Use Against Bursal Disease,
Marek's Disease, and Newcastle Disease, 5412–5413
Field Testing of a Vaccine for Use Against Newcastle
Disease and Marek's Disease, 5410–5411

Antitrust Division

NOTICES

Response to Public Comment:
United States, et al. v. CVS Health Corp. and Aetna Inc.,
5466–5477

Census Bureau

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals:
2019 National Survey of Psychiatrists, 5414–5415

Centers for Disease Control and Prevention

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 5439–5441
Meetings:
Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel, 5445–5446
Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel—IP19–001, Surveillance for
Respiratory Syncytial Virus and Other Viral
Respiratory Infections Among Native Americans/
Alaskan Natives; IP19–002, etc., 5445–5446
National Health and Nutrition Examination Survey DNA
Specimens:
Guidelines for Proposals to Use Samples and Cost
Schedule, 5441–5445

Centers for Medicare & Medicaid Services

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 5446–5447

Children and Families Administration

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 5447–5448

Civil Rights Commission

NOTICES

Meetings:
Oklahoma Advisory Committee, 5413–5414
Vermont Advisory Committee, 5414

Coast Guard

RULES

Safety Zones:
Pensacola Bay, Pensacola Beach, FL, 5354–5356

NOTICES

Agency Information Collection Activities; Proposals,
Submissions, and Approvals, 5458–5459

Commerce Department

See Census Bureau

See Economic Analysis Bureau

See Foreign-Trade Zones Board

See International Trade Administration

See National Institute of Standards and Technology

See National Oceanic and Atmospheric Administration

Copyright Royalty Board**NOTICES**

Distribution of Cable Royalty Funds; Correction, 5505–5506

Defense Department

See Air Force Department

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Labor-Related Requirements, 5436–5438

Drug Enforcement Administration**PROPOSED RULES**

New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances, 5395–5403

NOTICES

Bulk Manufacturer of Controlled Substances Application:

Johnson Matthey, Inc., 5477–5478

Navinta, LLC, 5498–5499

Noramco, Inc., 5499

Research Triangle Institute, 5501

Stepan Co., 5499

Bulk Manufacturer of Controlled Substances; Registration, 5478, 5499–5500

Decisions and Orders:

Ajay S. Ahuja, M.D., 5479–5498

Importer of Controlled Substances; Registration, 5477–5479, 5500

Economic Analysis Bureau**NOTICES**

Meetings:

American Workforce Policy Advisory Board, 5416

Education Department**NOTICES**

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

Case Service Report, 5428

Case Service Report; Correction, 5428

Meetings:

National Assessment Governing Board, 5426–5428

Employment and Training Administration**NOTICES**

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

Apprenticeship Powered by Industry Data Collection, 5504–5505

Energy Department

See Federal Energy Regulatory Commission

RULES

Administrative Updates to Personnel References, 5347–5350

Energy Conservation Program:

Test Procedures for Cooking Products and Test

Procedures for Portable Air Conditioners;

Corrections, 5346–5347

NOTICES

Meetings:

Electricity Advisory Committee, 5429

Hydrogen and Fuel Cell Technical Advisory Committee; Correction, 5429

Environmental Protection Agency**NOTICES**

Proposed Good Samaritan Settlement Agreement and Order on Consent for Removal Action:

Corona/Twin Peaks Mine Site, Napa County, CA, 5432–5433

Requests for Nominations:

Great Lakes Advisory Board, 5431–5432

Local Government Advisory Committee, 5433–5434

Farm Credit Administration**PROPOSED RULES**

Young, Beginning, and Small Farmers and Ranchers, 5389–5392

Federal Aviation Administration**RULES**

Airworthiness Directives:

Pacific Aerospace Limited Airplanes, 5350–5352

Amendment of Class E Airspace:

Carrizo Springs, TX, 5352–5353

PROPOSED RULES

Amendment of Class E Airspace:

Charleston, MO, 5392–5393

NOTICES

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

Specific Release Form, 5540–5541

Federal Deposit Insurance Corporation**PROPOSED RULES**

Assessments, 5380–5389

NOTICES

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

National Survey of Unbanked and Underbanked Households, 5434–5435

Federal Energy Regulatory Commission**NOTICES**

Combined Filings, 5429–5431

Federal Maritime Commission**NOTICES**

Agreements Filed, 5435–5436

Federal Motor Carrier Safety Administration**NOTICES**

Commercial Driver's License Standards; Exemption Applications:

Isuzu North America Corp. (Isuzu), 5543–5544

Hours of Service of Drivers:

WestRock, Application for Renewal of Exemption, 5546–5548

Parts and Accessories Necessary for Safe Operation:

Application for an Exemption from Stoneridge, Inc., 5557–5560

Qualification of Drivers; Exemption Applications:

Diabetes; Withdrawal of Notices of Final Disposition, 5549–5550

Epilepsy and Seizure Disorders, 5541–5542, 5548–5549, 5552–5554

Hearing, 5544–5546

Vision, 5550–5552, 5554–5557

Federal Reserve System**NOTICES**

Changes in Bank Control:

Acquisitions of Shares of a Bank or Bank Holding Company, 5436

Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 5436

Fish and Wildlife Service**NOTICES**

Application for an Incidental Take Permit:

Amended Habitat Conservation Plan; Piping Plover, Massachusetts Division of Fisheries and Wildlife; Draft Finding of No Significant Impact, 5460–5462

Recovery Permit Applications:

Endangered Species, 5462–5464

Food and Drug Administration**NOTICES**

Guidance:

Use of Investigational Tobacco Products, 5448–5453

Foreign-Trade Zones Board**NOTICES**

Authorization of Production Activity:

International Flavors and Fragrances, Inc.; Foreign-Trade Zone 44; Trenton, NJ, 5416

Forest Service**NOTICES**

Meetings:

Eastern Region Recreation Resource Advisory Committee, 5413

General Services Administration**NOTICES**

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

Labor-Related Requirements, 5436–5438

Health and Human Services Department

See Agency for Healthcare Research and Quality

See Centers for Disease Control and Prevention

See Centers for Medicare & Medicaid Services

See Children and Families Administration

See Food and Drug Administration

See Health Resources and Services Administration

Health Resources and Services Administration**NOTICES**

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

Maternal and Child Health Jurisdictional Survey Instrument for the Title V Maternal and Child Health Block Grant Program, 5455–5457

Meetings:

Advisory Committee on Interdisciplinary, Community-Based Linkages, 5457–5458

National Advisory Council on Migrant Health, 5453

National Vaccine Injury Compensation Program:

List of Petitions Received, 5453–5455

Homeland Security Department

See Coast Guard

See U.S. Citizenship and Immigration Services

Indian Affairs Bureau**NOTICES**

Application Deadlines:

Tribal Self-Governance Program in Fiscal Year 2020 or Calendar Year 2020, 5464–5465

Interior Department

See Fish and Wildlife Service

See Indian Affairs Bureau

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates, 5417–5419

International Trade Commission**NOTICES**

Meetings; Sunshine Act, 5465

Justice Department

See Alcohol, Tobacco, Firearms, and Explosives Bureau

See Antitrust Division

See Drug Enforcement Administration

NOTICES

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

2018 Census of Medical Examiner and Coroner Offices, 5501–5502

Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, 5502

Methodological Research to Support the National Crime Victimization Survey Redesign Program: National Survey of Crime and Safety—Field Test, 5502–5503

Survey of Law Enforcement Personnel in Schools, 5504

Labor Department

See Employment and Training Administration

Library of Congress

See Copyright Royalty Board

National Aeronautics and Space Administration**NOTICES**

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

Labor-Related Requirements, 5436–5438

National Institute of Standards and Technology**NOTICES**

Meetings:

Advisory Committee on Earthquake Hazards Reduction, 5419–5420

National Cybersecurity Center of Excellence Critical Cybersecurity Hygiene: Patching the Enterprise Building Block, 5420–5421

National Oceanic and Atmospheric Administration**RULES**

Atlantic Highly Migratory Species:

Shortfin Mako Shark Management Measures; Final Amendment 11, 5358–5377

Fisheries of the Northeastern United States:

Summer Flounder Fishery; Quota Transfer, 5377–5378

Pacific Island Fisheries:

Northwestern Hawaiian Islands Lobster Harvest Guideline, 5378

Pacific Island Pelagic Fisheries:

False Killer Whale Take Reduction Plan; Closure of Southern Exclusion Zone, 5356–5358

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 5424

Meetings:

Caribbean Fishery Management Council, 5423
 Gulf of Mexico Fishery Management Council, 5425–5426
 Mid-Atlantic Fishery Management Council, 5425–5426
 North Pacific Fishery Management Council, 5425
 Pacific Fishery Management Council, 5421–5423

National Science Foundation**NOTICES**

Meetings:

Proposal Review Panel for Physics, 5506

Presidential Documents**ADMINISTRATIVE ORDERS**

Cuba; Continuation of National Emergency With Respect to the Regulation of Anchorage and Movement of Vessels (Notice of February 19, 2019), 5577–5579

Libya; Continuation of National Emergency (Notice of February 19, 2019), 5581–5582

Securities and Exchange Commission**PROPOSED RULES**

Updated Disclosure Requirements and Summary Prospectus for Variable Annuity and Variable Life Insurance Contracts:

Reopening of Comment Period, 5393–5395

NOTICES

Self-Regulatory Organizations; Proposed Rule Changes:

BOX Exchange, LLC, 5521–5523, 5538–5540
 Cboe BZX Exchange, Inc., 5506–5508
 Cboe EDGX Exchange, Inc., 5515–5517
 Cboe Exchange, Inc., 5517–5519
 Fixed Income Clearing Corp., 5523–5524
 Miami International Securities Exchange, LLC, 5524–5526
 Municipal Securities Rulemaking Board, 5513–5515
 Nasdaq BX, Inc., 5532–5536
 Nasdaq GEMX, LLC, 5511–5513
 Nasdaq MRX, LLC, 5508–5511
 Nasdaq PHLX, LLC, 5526–5528
 New York Stock Exchange, LLC, 5536–5538

NYSE National, Inc., 5519–5521

The Nasdaq Stock Market, LLC, 5528–5532

Surface Transportation Board**NOTICES**

Railroad Cost of Capital – 2018, 5540

Transportation Department

See Federal Aviation Administration

See Federal Motor Carrier Safety Administration

PROPOSED RULES

Maintenance of and Access to Records Pertaining to Individuals; Correction, 5403

Treasury Department**NOTICES**

Interest Rate Paid on Cash Deposited to Secure U.S.

Immigration and Customs Enforcement Immigration Bonds, 5560

Social Impact Partnerships to Pay for Results Act Demonstration Projects, 5560–5576

U.S. Citizenship and Immigration Services**NOTICES**

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

Freedom of Information/Privacy Act Request, 5459–5460

Separate Parts In This Issue**Part II**

Presidential Documents, 5577–5579, 5581–5582

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.

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CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR**Administrative Orders:**

Notices:

Notice of February 19, 2019	5579
Notice of February 19, 2019	5581

7 CFR

1206	5335
------------	------

Proposed Rules:

1206	5379
------------	------

10 CFR

430	5346
903	5347

12 CFR**Proposed Rules:**

327	5380
614	5389

14 CFR

39	5350
71	5352

Proposed Rules:

71	5392
----------	------

17 CFR**Proposed Rules:**

230	5393
232	5393
239	5393
240	5393
270	5393
274	5393

21 CFR**Proposed Rules:**

1305	5395
------------	------

32 CFR

807	5353
813	5353
884	5354

33 CFR

165	5354
-----------	------

49 CFR**Proposed Rules:**

10	5403
----------	------

50 CFR

229	5356
635	5358
648	5377
665	5378

Rules and Regulations

Federal Register

Vol. 84, No. 35

Thursday, February 21, 2019

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

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Document No. AMS–SC–17–0002]

Mango Promotion, Research and Information Order; Amendment To Include Frozen Mangos

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the Agricultural Marketing Service's (AMS) regulations regarding a fresh mango national research and promotion program to include frozen mangos as a covered commodity under the Mango Promotion, Research and Information Order. The importers of frozen mangos will be assessed one cent (\$0.01) per pound on frozen mangos. Also, the National Mango Board's (Board) membership will be expanded from 18 to 21 with the addition of two importers of frozen mangos and one foreign processor.

DATES: Effective March 25, 2019.

Collection and remittance of frozen mangos assessments and applicable reporting will begin July 22, 2019.

FOR FURTHER INFORMATION CONTACT: Jeanette Palmer, Marketing Specialist, Promotion and Economics Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 720–9915; facsimile: (202) 205–2800; email: Jeanette.Palmer@ams.usda.gov.

SUPPLEMENTARY INFORMATION: This final rule affecting 7 CFR part 1206 is authorized under the Commodity Promotion, Research, and Information Act of 1996 (1996 Act) (7 U.S.C. 7411–7425).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules and promoting flexibility. This action falls within a category of regulatory actions that the OMB exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled "Reducing Regulation and Controlling Regulatory Costs" (February 2, 2017).

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12988

In addition, this final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have a retroactive effect. Section 524 of the 1996 Act (7 U.S.C. 7423) provides that it shall not affect or preempt any other Federal or State law authorizing promotion or research relating to an agricultural commodity.

Under section 519 of the 1996 Act (7 U.S.C. 7418), a person subject to an order issued under the Act may file a written petition with USDA stating that the order, any provision of the order, or any obligation imposed in connection with the order, is not established in accordance with the law, and request a modification of the order or an exemption from the order. Any petition filed challenging an order, any provision of an order, or any obligation

imposed in connection with an order, shall be filed within two years after the effective date of an order, provision, or obligation subject to challenge in the petition. The petitioner will have the opportunity for a hearing on the petition. Thereafter, USDA will issue a ruling on the petition. The Act provides that the district court of the United States for any district in which the petitioner resides or conducts business shall have jurisdiction to review a final ruling on the petition, if the petitioner files a complaint for that purpose not later than 20 days after the date of the entry of USDA's final ruling.

Background

This rule amends the AMS' regulations regarding a fresh mango national research and promotion program to include frozen mangos as a covered commodity. The program is administered by the Board with oversight by USDA. This rule will add definitions to the regulations for "frozen mangos" and "foreign processor of frozen mangos"; expand the Board's membership from 18 to 21 by adding two importers of frozen mangos and one foreign processor of frozen mangos; assess frozen mangos at a rate of \$0.01 per pound; exempt from assessment importers who import less than 200,000 pounds of frozen mangos annually; and make clarifying and conforming changes to other provisions of the program. This action was recommended by the Board in November 2016 and will allow frozen mango stakeholders to participate in a coordinated effort to maintain and expand the market for frozen mangos. This rule will also update the definition for the term "Board" to reflect current practices. Additionally, AMS has requested approval by OMB for the new information collection requirements necessary to include frozen mangos under the program.

Overview of Current Mango Program

The fresh mango research and promotion program took effect in November 2004 (69 FR 59120) and assessment collection began in January 2005. Under the current program, assessments are collected from first handlers and importers of 500,000 pounds or more of fresh mangos annually. Assessments are used by the Board for projects designed to maintain

and expand existing markets for fresh mangos in the United States.

Table 1 below shows the volume, value and price per pound for fresh mango imports into the United States from 2005 through 2016.¹ Imports of

fresh mangos have increased from about 575 million pounds in 2005 (valued at about \$169 million) to almost 985 million pounds in 2016 (valued at \$420 million). The price per pound for fresh mango imports has increased from \$0.29

in 2005 to \$0.43 in 2016. In 2016, about 45 percent of the mangos imported into the United States were from Mexico, 22 percent were from Ecuador, and 18 percent were from Peru.

TABLE 1—VOLUME, VALUE AND PRICE/POUND FOR FRESH MANGO IMPORTS 2005–2016

Year	Imports (pounds) (A)	Value (B)	Price/pound (C)
2016	984,554,112	\$420,291,061	\$0.43
2015	861,384,226	401,260,865	0.47
2014	827,108,732	372,298,536	0.45
2013	766,477,061	296,953,865	0.39
2012	706,690,535	248,410,276	0.35
2011	810,404,105	284,744,341	0.35
2010	706,690,535	248,410,276	0.35
2009	633,703,998	217,448,516	0.34
2008	655,825,602	210,884,833	0.32
2007	650,918,405	196,062,305	0.30
2006	644,579,545	209,650,045	0.33
2005	575,057,320	169,117,171	0.29

Column C equals Column B divided by Column A.

Assessment revenue under the fresh mango program increased from \$3,293,825² in 2007 to \$7,374,170³ in 2016. In 2016, less than one percent of the total assessments were from domestic handlers as the vast majority of assessments were collected from importers. The current assessment rate under the program for fresh mangos is \$0.0075 per pound, pursuant to § 1206.42(b).

Since 2008, the Board has invested over \$34 million of industry funds to help increase mango consumption among U.S. consumers. The Board has funded promotional programs with consumers, retailers and restaurants within the United States. Retail stores of all sizes are promoting mangos all year round, while restaurants all over the country are offering their customers more mango dishes. Consumers are

learning more about mangos from multiple media sources and the demand for mangos increased partly due to the Board's investments in educating consumers about the health benefits of eating mangos.

There have been two economic studies done since the program's inception in 2004 that assessed the effectiveness of the Board's programs. The studies were conducted by Dr. Ronald Ward at the University of Florida and published in 2011 and 2016 and are titled "*Estimating the Impact of the National Mango Board's Programs on the U.S. Demand for Mangos.*" The 2016 study built on the 2011 study and found that, for each dollar spent by the Board, approximately 11 to 12 times that was generated in sales. This return on investment indicates the program's success in increasing the demand for

mangos. The studies are available from USDA or the Board.

Frozen Mango Data

Table 2 below shows the volume, value and price per pound of frozen mango imports into the United States from 2005 through 2016.⁴ Imports of frozen mangos have increased from almost 32 million pounds in 2005 (valued at about \$14 million) to almost 118 million pounds in 2016 (valued at \$101 million). The price per pound of frozen mango imports has increased from \$0.46 in 2005 to \$0.86 in 2016. In 2016, over half of the imports of frozen mangos into the United States were from Mexico, 33 percent were from Peru, and 2 percent were from Guatemala.

TABLE 2—VOLUME, VALUE AND PRICE/POUND FOR FROZEN MANGO IMPORTS 2005–2016

Year	Imports (pounds) (A)	Value (B)	Price/pound (C)
2016	117,724,239	\$101,204,418	\$0.86
2015	139,492,136	131,155,555	0.94
2014	116,950,534	82,257,399	0.70
2013	128,109,849	80,929,782	0.63
2012	91,630,515	54,466,961	0.59
2011	88,121,973	49,291,591	0.56
2010	64,688,410	38,581,629	0.60
2009	30,178,419	21,619,646	0.72
2008	51,756,422	32,298,845	0.62
2007	52,832,786	29,982,510	0.57
2006	44,351,020	22,447,677	0.51
2005	31,657,933	14,473,533	0.46

Column C equals Column B divided by Column A.

¹ <https://apps.fas.usda.gov/gats/default.aspx>.

² National Mango Promotion Board, Financial Statements Year Ending December 31, 2007; Cross,

Fernandez & Riley, LLP, Accountants and Consultants; April 18, 2008; p. 13.

³ National Mango Promotion Board, Financial Statements and Supplementary Information Years

Ending December 31, 2016 and 2015; BDO USA, LLP; March 15, 2017; p. 17.

⁴ <https://apps.fas.usda.gov/gats/default.aspx>.

Board Recommendation

Because of the current program’s success at increasing the fresh mango market, those who sell frozen mangos have been interested in becoming part of the program. Mango producers often sell their mangos for use by both the fresh and processed markets. Handlers and importers may include all mango product categories in their businesses. However, current Board promotion efforts only support mangos for the fresh market.

Thus, the Board recommended amending part 1206 to include frozen mangos. This will allow frozen mango stakeholders to participate in a coordinated effort to maintain and expand the existing market for frozen mangos. These efforts will be accomplished through Board activities including promotion, research, consumer information, education and industry information. By collaborating within the existing national mango promotion program, frozen mango stakeholders can provide to consumers more information on the various uses and benefits of frozen mangos in order to increase demand for the commodity.

Accordingly, several changes to part 1206 will be necessary to expand the program to include frozen mangos. These changes are described in the following paragraphs. Authority for the Board to recommend changes to part 1206 is provided in § 1206.36(m).

Definitions

Frozen Mangos

The term “mangos” is defined in § 1206.11 to mean all *fresh* fruit of *Mangifera indica L.* of the family *Anacardiaceae*. The term will be revised to mean the fruit of *Mangifera indica L.* of the family *Anacardiaceae* and will include both fresh and frozen mangos. Separate definitions will be added in new paragraphs (a) and (b) of § 1206.11 for fresh and frozen mangos, respectively. “Fresh mangos” will mean mangos in their fresh form. “Frozen mangos” will mean mangos which are uncooked or cooked by steaming or boiling in water, and then frozen, whether or not containing added sugar or other sweetening agent.

Foreign Processor of Frozen Mangos

A definition will be added to part 1206 for “foreign processor of frozen mangos.” Section 1206.8, which currently defines the term “foreign producer” will be redesignated as § 1206.8a, and a new § 1206.8 will define the term “foreign processor of frozen mangos” or “foreign processor” to mean any person: (a) Who is engaged in the preparation of frozen mangos for market to the United States and/or who owns or shares the ownership and risk of loss of such mangos; and (b) who exports frozen mangos to the United States. As described later in this document, a foreign processor will have a seat on the Board.

Additionally, §§ 1206.6 and 1206.9, which define the terms “first handler” and “importer,” respectively, to mean

entities that handle or import 500,000 pounds or more of mangos annually will be revised to remove the references to volume. There are other sections in part 1206 that apply to all first handlers and importers regardless of the volume of mangos handled or imported (*i.e.*, § 1206.61 regarding books and records and § 1206.62 regarding confidential treatment thereof). Thus, the definition of the terms “first handler” and “importer” will be revised to mean *all* such entities, regardless of the volume of mangos handled or imported. Other sections of part 1206 where the volume handled or imported is relevant will specify the applicable figure.

Mango Board

Establishment and Membership

Section 1206.30(a) regarding establishment and membership of the Board specifies that the Board be composed of 18 members—8 importers, 1 first handler, 2 domestic producers and 7 foreign producers. This section will be revised to add three Board seats—two for importers of frozen mangos and one for a foreign processor of frozen mangos.

The Board’s rationale for recommending the addition of three seats representing the frozen mango industry is based on a review of import data. Table 3 below shows fresh and frozen mango import data for 2014–2016.⁵ Fresh and frozen mango imports account for an average of 88 and 12 percent, respectively, of the total volume of mango imports for the 3-year period.

TABLE 3—FRESH AND FROZEN MANGO IMPORT VOLUMES 2014–2016

Year	Fresh mango imports (pounds)	Frozen mango imports (pounds)	Total fresh and frozen mango imports (pounds)
2016	984,554,112	117,724,239	1,102,278,350
2015	861,384,226	139,492,136	1,000,876,362
2014	827,108,732	116,950,534	944,059,266
3-Year Average	891,015,690	124,722,303	1,015,737,993
Percent of Total	88 percent ¹	12 percent ²	

¹ This figure equals the 3-year average of 891,015,690 for fresh mango imports divided by the total mango import figure of 1,015,737,993, multiplied by 100.

² This figure equals the 3-year average of 124,722,303 for frozen mango imports divided by the total mango import figure of 1,015,737,993, multiplied by 100.

Imports of fresh mangos account for over 99 percent of the assessments under the current program. On the current 18-member Board, 15 out of the 18 seats (about 83 percent) are for importers and foreign producers. If three Board seats are added to represent

frozen mango imports (two importers and one foreign processor), then 18 of the new 21-member Board (almost 87 percent) will represent foreign mangos. Further, 3 of the 18 foreign-product seats (importers and foreign producers) will represent frozen imported mangos

(almost 17 percent) and the remaining 15 seats (over 83 percent) will represent fresh imported mangos. USDA concludes that the Board’s recommendation regarding frozen mango representation on the Board is

⁵ <https://apps.fas.usda.gov/gats/default.aspx>.

reasonable and § 1206.30(a) will be revised accordingly.

Additionally, a sentence will be added to § 1206.30(a) to specify that first handler Board members must receive 500,000 pounds or more of fresh mangos annually from producers, and importer Board members must import 500,000 pounds or more of fresh mangos or 200,000 pounds or more of frozen mangos annually. These requirements are part of the current de minimis exemption for the program (see § 1206.43 Exemptions), added to the Establishment and Membership section in § 1206.30 for clarification as to who is covered under the program.

Section 1206.30(b) defines Customs Districts within the United States that are used for allocating importer Board seats based on the volume of mangos imported into each respective district. This section will be revised to state that the two Board seats for importers of frozen mangos shall be allocated for importers who import into any of the districts (or “at-large”) defined in paragraphs (1) through (4) of § 1206.30(b). The Board recommended that these two seats be at-large to allow nominees from all four districts. This can encourage participation on the Board from this new importer group regardless of their location.

Nominations and Appointments

Section 1206.31 prescribes procedures for nominating and appointing Board members. Board staff solicits nominees for first handler, fresh mango importer, and domestic producer member positions and voting is conducted by mail ballot. Nominees to fill the foreign producer member positions are solicited from foreign producers and from foreign producer organizations. From the nominations, the Secretary of Agriculture (Secretary) then selects the members of the Board.

This section will be revised to specify procedures for nominating foreign processors and importers of frozen mangos. The procedures will be similar to those in place for first handlers and importers of fresh mangos. Nominees to fill the foreign processor seat will be

solicited from foreign mango organizations and from foreign processors. Foreign mango organizations will submit two nominees for each position, and foreign processors can submit their own name or the names of other foreign processors directly to the Board. The nominees will represent the major countries exporting frozen mangos to the United States.

Nominees to fill the two at-large seats on the Board will be solicited from all known importers of frozen mangos. The members from each district will select the nominees for the two at-large positions on the Board. Two nominees will be submitted for each position. The names of the nominees will be placed on a ballot that will be sent to importers of frozen mangos in each of the four districts for a vote. For each position, the nominee receiving the highest number of votes and the nominee receiving the second highest number of votes will be submitted to USDA as the first and second choice nominees.

Accordingly, in § 1206.31, paragraph (e), which prescribes nomination procedures for fresh mango importers, will be revised to clarify that the procedures pertain to *fresh* mango importers. Further, paragraph (h) will be redesignated as paragraph (k), a new paragraph (h) will be added to specify procedures for nominating foreign processors, and a new paragraph (i) will be added to specify procedures for nominating frozen mango importers.

A new paragraph (j) will be added to § 1206.31 to clarify that first handler nominees for a Board position must receive more than 500,000 pounds of fresh mangos annually from producers, and importers must import 500,000 pounds or more of fresh mangos annually or 200,000 pounds or more of frozen mangos annually.

Term of Office

Section 1206.32 specifies that Board members serve for a 3-year term of office. Members may serve a maximum of two consecutive 3-year terms. This section will be revised to include the new positions for importers of frozen mangos and foreign processors. Similar

to the other Board members, the term of office for the new positions will be 3 years, and no member can serve on the Board for more than two consecutive 3-year terms.

Procedure

Section 1206.34(a) specifies that a quorum for the current 18-member Board consists of 10 members. This rule will increase the number of Board seats from 18 to 21, which necessitates an increase in quorum requirements. Therefore, this section will be revised to specify that a quorum at a Board meeting exists when at least 11 of the 21 Board members are present.

Assessments

Section 1206.42(b) specifies that the assessment rate is three quarters of a cent (\$0.0075) per pound on all mangos (fresh). Pursuant to paragraph (d) of § 1206.42, import assessments are collected through U.S. Customs and Border Protection (Customs). Pursuant to paragraph (e) of that section, first handlers must submit their assessments to the Board on a monthly basis.

In its deliberations on the proposed assessment rate for frozen mangos, the Board considered the current assessment rate for fresh mangos of \$0.0075 per pound. Board members took into account that it takes 2.5 pounds of fresh mangos to make one pound of frozen mangos.⁶ If the fresh equivalent assessment rate were applied to frozen mangos, frozen mango importers would pay an assessment of approximately \$0.019 per pound, which is 2.5 times the fresh mango assessment rate. Additionally, according to the Board, manufacturing costs are higher for frozen mangos than for fresh mangos because the fruit has been processed.

The Board also considered assessment revenue as a percentage of value. Board members refer to this computation as the “Mango Reinvestment Rate” or MRR. To compute this for fresh mangos, assessment revenue is divided by the value of imported fresh product. The 3-year average for 2014–2016 for fresh mangos is 1.71 percent. The computation is shown in Table 4 below.

TABLE 4—ASSESSMENT REVENUE AS PERCENTAGE OF VALUE FOR FRESH MANGOS

Year	Assessment revenue (A)	Value (B)	Revenue as a percent of value (C)
2016	\$7,374,170	\$101,204,418	1.75
2015	6,785,156	131,155,555	1.69

⁶ Kader, Adel A.; Fresh Cut Mangos as a Value-Added Product (Literature Review and Interviews); October 2, 2008; page 20.

TABLE 4—ASSESSMENT REVENUE AS PERCENTAGE OF VALUE FOR FRESH MANGOS—Continued

Year	Assessment revenue (A)	Value (B)	Revenue as a percent of value (C)
2014	6,249,918	82,257,399	1.68
3-yr average			1.71

Column C is computed by dividing Column A by Column B, and multiplying that figure by 100.

The 1.71 percent MRR was shared with importers and processors of frozen mangos. A majority of the importers and processors contacted indicated that, while the MRR computation seems equitable, expenses are higher and the profit margins are lower for frozen

mangos. The industry members contacted indicated that a MRR between 1.0 and 1.5 percent was more in line with what they saw as equitable for the frozen mango industry.

Thus, the Board ultimately recommended an assessment rate for frozen mangos of \$0.01 per pound. As

shown in Table 5 below, this computes to an average MRR of 1.21 percent for 2014–2016. Additionally, only imports of frozen mangos will be assessed at this rate because first handlers in the United States receive only fresh mangos from producers.

TABLE 5—PROJECTED ASSESSMENT REVENUE AS PERCENTAGE OF VALUE FOR FROZEN MANGOS

Year	Imports (pounds) (A)	Value (B)	Assessment rate (per pound) (C)	Projected assessment revenue (D)	Revenue as a percent of value (E)
2016	117,724,239	\$101,204,418	\$0.01	\$1,177,242	1.16
2015	139,492,136	131,155,555	0.01	1,394,921	1.06
2014	116,950,534	82,257,399	0.01	1,169,505	1.42
3-yr average					1.21

Column D is computed by multiplying Column B by Column C.

Column E is computed by dividing Column A by Column B, and multiplying that figure by 100.

Accordingly, in § 1206.42, paragraph (b) will be revised to specify an assessment rate of \$0.01 per pound for frozen mangos, and paragraph (d)(2) will be revised to include the numbers for frozen mangos listed in the Harmonized Tariff Schedule (HTS) of the United States and update the HTS numbers for fresh mango imports. Section 517(d) of the 1996 Act (7 U.S.C. 7416) provides authority for one or more rates of assessment to be levied under a research and promotion program.

Exemptions

Section 1206.43 specifies that first handlers and importers of less than 500,000 pounds of mangos (fresh) may claim an exemption from the assessment obligation. The Board recommended revising the section to specify that importers of less than 200,000 pounds of frozen mangos be exempt from assessment. This amount was derived by taking into account the ratio for converting fresh mangos into frozen mangos (2.5 pounds of fresh to make 1 pound of frozen). Multiplying the factor 0.4 (1 pound frozen divided by 2.5 pounds fresh) by the fresh mango exemption of 500,000 pounds computes to 200,000 pounds. Paragraphs (a) and (b) in § 1206.43 will be revised

accordingly. (First handlers only receive fresh mangos from domestic producers. Thus, the exemption threshold for frozen mangos will only apply to importers.)

Subpart B of part 1206 specifies procedures for conducting a referendum. In § 1206.101, paragraphs (c) and (d), respectively, define eligible first handlers and importers as those that handle or import 500,000 pounds or more of mangos (fresh) annually. This section will be revised to specify that importers of 200,000 pounds or more of frozen mangos will be eligible to vote in referenda.

Further, this rule will revise the term “Board” as defined in § 1206.2 from the “National Mango Promotion Board” to “National Mango Board” to reflect current practices. The term as it appears in § 1206.30 and in the undesignated heading preceding § 1206.30 will also be revised to read “National Mango Board.” Finally, this rule will update the OMB control number specified in § 1206.78 from 0581–0209 to 0581–0093.

Final Regulatory Flexibility Act Analysis

In accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS is required to examine the

impact of the final rule on small entities. Accordingly, AMS has considered the economic impact of this action on such entities.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be disproportionately burdened. The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than \$750,000 and small agricultural service firms (first handlers and importers) as those having annual receipts of no more than \$7.5 million.

According to the Board, there are five first handlers of fresh mangos. Based on 2016 assessment data, the majority of first handlers handled less than \$7.5 million worth of fresh mangos and would thus be considered small entities.

Based on 2016 Customs data,⁷ there are about 275 importers of fresh mangos and 190 importers of frozen mangos. The majority of fresh and frozen mango importers import less than \$7.5 million worth of fresh or frozen mangos and would also be considered small entities.

This rule amends AMS’ regulations regarding a fresh mango national

⁷ <https://www.cbp.gov/trade/automated>.

research and promotion program to include frozen mangos as a covered commodity. The program is administered by the Board with oversight by USDA. This rule will add definitions for frozen mangos (§ 1206.11) and foreign processor of frozen mangos (§ 1206.8); expand the Board's membership from 18 to 21 by adding two importers of frozen mangos and one foreign processor of frozen mangos (§§ 1206.30 and 1206.31); assess frozen mangos at a rate of \$0.01 per pound (§ 1206.42); exempt from assessment importers who import less than 200,000 pounds of frozen mangos annually (§ 1206.43); and make clarifying and conforming changes to other provisions in part 1206 (revisions will be made to clarify the definitions for first handler (§ 1206.6) and importer (§ 1206.9); quorum requirements will be revised (§ 1206.34); and definitions for importers eligible to vote in referenda will be revised (§ 1206.101)). Authority for amending part 1206 is provided in § 1206.36(m) and in section 514 of the 1996 Act. This rule will also update the definition of term "Board" to reflect current practices (§ 1206.2, the heading preceding § 1206.30, and § 1206.30). Section 1206.2 provides authority for revising the term "Board." Finally, this rule will update one of the OMB numbers (0581-0209) listed in § 1206.78.

Mango producers are not subject to assessment under the program. Currently, first handlers and importers of less than 500,000 pounds of fresh mangos annually are exempt from assessment. Further, organic mangos and exports of U.S. mangos are also exempt from assessment under the program.

Regarding the economic impact of this rule on affected entities, importers of 200,000 pounds or more of frozen mangos annually will pay an assessment of \$0.01 per pound. Based on Customs⁸ data, of the 190 importers of frozen mangos, about 60 imported 200,000 pounds or more in 2016 and will pay assessments, and thus 130 importers imported less than 200,000 pounds and will be exempt from paying assessments under the program. Exempt importers will be able to apply to the Board for a refund of assessments funds collected by Customs. Those requirements are detailed in the section of this document titled Paperwork Reduction Act. (The update to the term Board is administrative in nature.)

Regarding the impact of this final rule action on the industry as a whole, as shown previously in Table 3, imports of

frozen mangos averaged about 125 million pounds annually from 2014–2016. At an assessment rate of \$0.01 per pound, this would equate to about \$1.25 million per year in assessment revenue.

Further, this rule will allow frozen mango stakeholders to participate in a coordinated effort to maintain and expand the existing market for frozen mangos in the United States. These efforts will be accomplished through Board activities including promotion, research, consumer information, education and industry information. By collaborating within the existing national mango promotion program, frozen mango stakeholders could provide to consumers more information on the various uses and benefits of frozen mangos in order to increase demand for the commodity.

With regard to alternatives, the Board contemplated the merits of collecting assessments for all processed mangos (*i.e.*, frozen as well as juice and concentrate). The Board's staff attended several process tradeshows, conferences, and other events to garner support for the mango program. After several outreach activities, the frozen mango industry demonstrated the highest positive response of the other process categories to be included under the mango program.

As for alternative assessment rates, as previously mentioned, the Board considered the current assessment rate for fresh mangos of \$0.0075 per pound. However, if the fresh equivalent assessment rate were applied to frozen mangos, frozen mango importers would pay an assessment of approximately \$0.019 per pound, which is 2.5 times the fresh mango assessment rate. (It takes 2.5 pounds of fresh mangos to make one pound of frozen mangos.) Additionally, according to the Board, manufacturing costs are higher for frozen mangos than for fresh mangos because the fruit has been processed.

The Board also considered assessment revenue as a percentage of value. Board members refer to this computation as the "Mango Reinvestment Rate" or MRR. To compute this for fresh mangos, assessment revenue is divided by the value of imported fresh product. The 3-year average for 2014–2016 for fresh mangos is 1.71 percent. The computation was shown previously in Table 4. The 1.71 percent MRR was shared with importers and processors of frozen mangos. A majority of the importers and processors contacted indicated that, while the MRR computation seems equitable, expenses are higher and the profit margins are lower for frozen mangos. Industry members contacted indicated that a

MRR between 1.0 and 1.5 percent was more in line with what they saw as equitable for the frozen mango industry. Thus, the Board ultimately recommended an assessment rate for frozen mangos of \$0.01 per pound. As shown previously in Table 5, this computes to an average MRR of 1.21 percent for 2014–2016.

The Board also considered alternative exemption thresholds. When the Board initially contemplated expanding the mango program, it considered including all categories of processed mangos, including juice, concentrate and frozen. Each of these categories has a different conversion ratio, or amount of fresh mangos that it takes to make the respective processed fruit. At that time, the Board considered an exemption threshold of 45,000 pounds. When the Board decided to pursue amending the program to include only frozen mangos, the Board also decided to recommend an exemption threshold of 200,000 pounds. This was based on the industry average ratio of 0.4 for converting fresh mangos into frozen mangos (2.5 pounds of fresh mangos to make one pound of frozen mangos). Multiplying the fresh mango exemption threshold of 500,000 pounds by the 0.4 ratio equals 200,000 pounds. Thus, the Board recommended an exemption threshold of 200,000 pounds for frozen mangos.

This action will impose additional reporting and recordkeeping requirements upon importers and processors of frozen mangos. Importers and foreign processors of frozen mangos eligible to and interested in serving on the Board must submit a nomination form to the Board indicating their desire to serve or nominate another industry member to serve on the Board. Importers can cast a ballot and vote for candidates to serve on the Board. Frozen mango importer and foreign processor nominees must submit a background form to the Secretary to ensure they are qualified to serve on the Board.

Additionally, importers of frozen mangos who import less than 200,000 pounds annually can request an exemption from paying assessments. Importers of organic frozen mangos can submit a request to the Board for an exemption from assessment for their organic mango imports. Importers can also request a refund of assessments paid through Customs.

Finally, frozen mango importers who want to participate in future referenda on the program will have to complete a ballot for submission to the Secretary.

New forms are required to collect the referenced information. These forms will be submitted to OMB for approval under OMB Control No. 0581-0314.

⁸ <https://www.cbp.gov/trade/automated>.

Specific burdens for the forms are detailed later in this document in the section titled Paperwork Reduction Act. As with all Federal promotion programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. Finally, there are no Federal rules that duplicate, overlap, or conflict with this rule.

In regard to outreach efforts, in 2015 the Board commissioned a survey to determine industry support for expanding the coverage of part 1206. Processed mango importers responded in favor of amending the program. The survey respondents represented 72 percent of the imported processed mango volume. The Board also hosted a webinar in June 2015 and invited all known importers of processed mangos to participate. Fifteen industry members participated in the webinar. Of the attendees, 95 percent supported expanding the program to include processed mangos. Two importers of frozen mangos participated in the Board's meeting in September 2015 where this issue was discussed.

In 2016, Board representatives attended tradeshows and conferences for processed fruit products in the U.S. and visited several mango producing regions and receiving ports in order to meet with processors and importers to discuss amending the program. Board representatives attended 21 meetings with frozen mango importers of record. The Board subsequently conducted another survey where 74 companies were contacted via electronic mail and telephone calls. Of the companies that participated in the survey, 71 percent were in favor of expanding the program to include frozen mangos. The Board continues to educate and update the mango industry on its marketing activities.

A proposed rule concerning this action was published in the **Federal Register** on April 6, 2018 (83 FR 14771). A notice was published on July 12, 2018 (83 FR 32215) to open and extend the comment period. The Board sent the proposed rule to the associations that represent the fresh mango associations. In addition, the Board disseminated the proposed rule via the internet by providing links to the proposal in its industry newsletter and website. The proposal was also made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending June 5, 2018, and a 30-day comment period extension ending August 13, 2018, which is a total of 90 days, were provided to allow interested persons to submit comments.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), AMS requested approval of the new information collection and recordkeeping requirements for the frozen mango industry. Information collection and recordkeeping requirements for the fresh mango program (part 1206) have previously been approved under OMB control nos. 0581-0093 and 0505-0001. AMS will submit a Justification for Change to merge this new burden for frozen mangos into the currently approved collection for fresh mangos.

Title: Frozen mango research, promotion and consumer information program.

OMB Number: 0581-0314.

Expiration Date of Approval: 3 years from approval date.

Type of Request: New information collection for research and promotion programs.

Abstract: The information collection requirements in the request are essential to carry out the intent of the 1996 Act. The information collection concerns a recommendation received by USDA to amend the fresh mango national research and promotion program (part 1206) to include frozen mangos. The program is currently financed by an assessment on first handlers and importers of 500,000 pounds or more fresh mangos annually. The program is administered by the Board with oversight by USDA.

In November 2016, the Board recommended amending part 1206 to include frozen mangos. Importers of 200,000 or more frozen mangos annually will pay assessments. The Board will be expanded from 18 to 21 members by adding two importers of frozen mangos and one foreign processor of frozen mangos. This action will allow frozen mango stakeholders to participate in a coordinated effort to maintain and expand the market for frozen mangos.

In summary, the information collection requirements regarding frozen mangos pertain to Board nominations, the collection of assessments, and referenda. Frozen mango importers and foreign processors interested in serving on the Board must submit a "Nomination Form" to the Board indicating their desire to serve or to nominate another industry member to serve on the Board. They can submit a "Nomination Ballot" to the Board where they will vote for candidates to serve on the Board. Also, nominees must submit a background information form, "AD-755," to the Secretary to ensure they are

qualified to serve. Frozen mango importers of less than 200,000 pounds annually can submit a request, "Application for Exemption from Assessments," to the Board and request a refund of any assessments paid using the form "Application for Reimbursement of Assessment." (Import assessments will be collected by Customs and remitted to the Board.) Importers of organic frozen mangos could also apply to the Board for an exemption from assessment. Finally, importers of frozen mangos will have the opportunity to vote in future referenda on the program.

This new information collection will impose a total burden of 167.37 hours and 287.48 responses for 190 respondents. New information collection requirements that are included in this rule pertaining to the frozen mango industry include:

(1) Nomination Form

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response.

Respondents: Importers of 200,000 pounds or more of frozen mangos annually and foreign processors.

Estimated Number of Respondents: 20.

Estimated Number of Responses per Respondent: .33 (1 every 3 years).

Estimated Total Annual Burden on Respondents: 1.65 hours.

(2) Nomination Ballot

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response.

Respondents: Importers of 200,000 pounds or more of frozen mangos annually and foreign processors.

Estimated Number of Respondents: 30.

Estimated Number of Responses per Respondent: .33 (1 every 3 years).

Estimated Total Annual Burden on Respondents: 2.48 hours.

(3) Application for Exemption From Assessments

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response. Upon approval, the applicant will receive exemption certification.

Respondents: Importers of less than 200,000 pounds of frozen mangos annually.

Estimated Number of Respondents: 130.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 32.5 hours.

(4) Application for Reimbursement of Assessment

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response.

Respondents: Importers of less than 200,000 pounds of frozen mangos annually.

Estimated Number of Respondents: 130.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 32.5 hours.

(5) Organic Exemption Request Form

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response.

Respondents: Importers of 200,000 pounds or more of organic frozen mangos annually.

Estimated Number of Respondents: 5.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 1.25 hours.

(6) Referendum Ballot

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.25 hour per response.

Respondents: Importers of 200,000 pounds or more of frozen mangos annually.

Estimated Number of Respondents: 20.

Estimated Number of Responses per Respondent: .20 (1 every 5 years).

Estimated Total Annual Burden on Respondents: 1.0 hours.

(7) Background Information Form AD-755 (OMB Form No. 0505-0001)

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.5 hour per response.

Respondents: Importers of 200,000 pounds or more of frozen mangos and foreign processors.

Estimated Number of Respondents: 6.

Estimated Number of Responses per Respondent: .33 (1 every 3 years).

Estimated Total Annual Burden on Respondents: 1.0 hour.

(8) A Requirement To Maintain Records Sufficient To Verify Reports Submitted Under Part 1206

Estimate of Burden: Public recordkeeping burden for keeping this information is estimated to average 0.5 hour per record keeper maintaining such records.

Recordkeepers: Importers of frozen mangos.

Estimated Number of Recordkeepers: 190 (130 exempt and 60 assessment payers).

Estimated Total Recordkeeping Hours: 95 hours.

An estimated 190 respondents will provide information to the Board. The estimated cost of providing the information to the Board by respondents would be \$2,870.90. This total has been estimated by multiplying 95 total hours required for reporting and recordkeeping by \$30.22, the average mean hourly earnings of importers. Data for computation of this hourly rate was obtained from the U.S. Department of Labor Statistics.

The revisions to the fresh mango program have been carefully reviewed, and every effort has been made to minimize any unnecessary recordkeeping costs or requirements, including efforts to utilize information already submitted under other programs administered by USDA and other state programs.

The forms require the minimum information necessary to effectively carry out the requirements of the program, and their use is necessary to fulfill the intent of the 1996 Act. Such information can be supplied without data processing equipment or outside technical expertise. In addition, there are no additional training requirements for individuals filling out reports and remitting assessments to the Board. The forms are simple, easy to understand, and place as small a burden as possible on the person required to file the information.

The information to be included on these forms is not available from other sources because such information relates specifically to individual importers and processors of frozen mangos who are subject to the provisions of the 1996 Act. Therefore, there is no practical method for collecting the required information without the use of these forms.

The proposed rule published on April 6, 2018, with a 60-day comment period ended on June 5, 2018. A notice was published on July 12, 2018, in the **Federal Register**, to reopen the comment period for an additional 30 days until August 13, 2018.

Additionally, comments were invited on the information collection requirements prescribed in the Paperwork Reduction Act section of this rule. The proposed rule provided for a 90-day comment period which ended August 13, 2018. No comments were received regarding the information collection.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other

information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Analysis of Comments

The proposed rule published in the **Federal Register** on April 6, 2018, provided a 60-day comment period that ended June 5, 2018. A notice published on July 12, 2018, reopened the comment period for an additional 30 days that ended on August 13, 2018. In total, nineteen comments were received. Of the 19 comments, 14 comments were in favor, 3 comments in opposition, and 2 commented without taking a position on the proposal. Two of the supporting comments were responding to a commenter who opposed the proposed amendment.

Comments in Support

In general, eight commenters in favor of the proposed rule agreed that the combined marketing efforts of the two industries will likely result in the greater demand for mango consumption for both industries. Also, three commenters stated by expanding the program to include frozen mangos, it would leverage mango exposure to consumers whether fresh or frozen in foodservice.

In addition, three commenters stated if the Board creates new opportunities for frozen mangos, consumers will discover the health benefits of frozen mangos and the ease of use, shelf stability, and consistency in supply which will help grow the mango industry as a whole.

One commenter stated an organization conducted a survey in 2014 of frozen mango companies and 68 percent of the frozen mango processing companies responded that promoting process mango would increase their sales. Of the U.S. respondents alone, 75 percent of companies believed promoting frozen mangos would improve sales.

Also, one commenter discussed how the Board spent several years and financial resources conducting outreach meetings to gauge the interest level of the mango processing community. The same commenter further states the Board staff attended a processed mango conference in multiple years to provide details on the proposed amendment and receive feedback from the conference attendees. Additionally, the same commenter states the goal of the proposed amendment is to strengthen the mango industry for fresh and frozen mango products which will benefit growers, processors, importers, and distributors in the mango industry.

One commenter stated that the Board considers the proposed assessment rate of \$0.01 per pound for frozen mangos to be equitable. The same commenter states the proposed three new seats on the Board should be proportional to the revenue that would be generated by adding frozen mangos to the program. In other words, if the proposed frozen mango assessment rate is lowered, the number of new Board seats should be reduced from three to two seats. The commenter believes this modification would be more in line with the additional funds that would be generated from the frozen mango assessment revenue at a lower assessment rate. USDA will not modify the assessment rate or reduce the number of new Board seats for the frozen mango importers and foreign processors because USDA believes the proposal submitted by the Board appears to be equitable based on the projected revenue that frozen mangos is expected to generate shown in Table 5.

In addition, the same commenter stated the decision to broaden the program to include frozen mangos should be decided in a referendum by those who will be subject to assessment under the expanded program, both fresh mango handlers and importers and frozen mango importers. USDA agrees. Section 518(d) of the 1996 Act (7 U.S.C. 7417(d)) states that the Secretary may conduct a referendum at any time to determine whether the continuation, suspension, or termination of the order or a provision of the order is favored by persons eligible to vote under the program. Once this final rule becomes effective, USDA will conduct a referendum to allow importers and handlers of fresh mangos and importers of frozen mangos to vote on whether they approve the continuation of the program with the inclusion of frozen mangos.

Comments Opposed

One commenter in opposition to the proposed rule stated that the more the Board promotes fresh mangos, the fewer mangos that are available to the frozen industry. As presented in the proposal, imports of frozen mangos have increased from almost 32 million pounds in 2005 (valued at about \$14 million) to almost 118 million pounds in 2016 (valued at \$101 million). The price per pound for frozen mango imports has increased from \$0.46 in 2005 to \$0.86 in 2016. Based on the data presented, frozen mango imports has increased during the Board's marketing promotions for fresh mangos.

Two commenters stated there would be a conflict to add frozen mangos to the

current fresh mango program. USDA does not perceive this proposal as a conflict of interest between the fresh and frozen mango industries. USDA provides oversight to other commodity boards such as the U.S. Highbush Blueberry Council and the National Potato Promotion Board that consist of both fresh and processed industry members. USDA's experience is that both fresh and processed commodity industries benefit from participation in a research and promotion program. The same commenters expressed concerns about how the Board would use the assessment revenue collected on imports of frozen mangos. When the Board begins the collection of assessments on the imports of frozen mangos, the Board which includes the new frozen members will develop a sound marketing strategy to promote frozen mangos which must be approved by USDA.

Furthermore, two commenters stated the proposed assessment rate of one cent per pound on frozen mangos was higher than the assessment rate of three quarters of a cent per pound on fresh mangos. The commenters argue that the additional cost of frozen mango product will make the product much less competitive in the marketplace. As stated in the proposal, in the Board's deliberations on the proposed assessment rate for frozen mangos, the Board considered the current assessment rate for fresh mangos of three quarters of a cent per pound. Board members took into account that it takes 2.5 pounds of fresh mangos to produce one pound of frozen mangos. If the fresh equivalent assessment rate were applied to frozen mangos, frozen mango importers would pay an assessment of approximately \$0.019 per pound, which is 2.5 times the fresh mango assessment rate. According to the Board, manufacturing costs are higher for frozen mangos than for fresh mangos because the fruit has been processed. The Board recommended an assessment rate for frozen mangos of one cent per pound. As shown in Table 5 of the proposal, this computes to an average MRR of 1.21 percent for 2014–2016. USDA accepts the Board's recommendation to assess frozen mangos at one cent per pound based on the data provided in Table 5 of the proposal.

Two commenters stated that other processed mango categories such as canned, dried, and concentrate mangos were not included in the proposal. As stated in the proposed rule, the Board contemplated the merits of assessing all processed mangos. The Board's staff attended several conferences,

tradeshows, and other events to garner support for the mango program. After the Board's outreach activities were conducted, the frozen mango industry demonstrated the highest level of interest of the other process categories to be included in the mango program. USDA accepts the Board's recommendation to include frozen mangos in the mango program.

Furthermore, one commenter stated that other processed mango categories such as canned, dried, and concentrate mangos would not be subject to assessments. This commenter is correct. The processed mangos categories for aseptic, canned, concentrate, and dried mangos will not be subject to assessments based on the proposed rule.

One commenter stated it was not clear whether the proposal to include frozen mangos is to augment the Board's annual assessment revenue or if the added revenue is expected to target specific frozen mango production strategies. As presented in the proposed rule, if frozen mango is included in the mango program and assessment collections begins, the Board will use the additional assessment revenue to maintain and expand the existing market for frozen mangos. These efforts would be accomplished through Board activities including promotion, research, consumer and industry information.

The same commenter stated the program does not outline any specific proposal that prioritizes frozen mangos in its future research and promotion programs. The specifics on how assessment funds would be invested to promote frozen mango are not outlined in the proposal because collection of assessments on frozen mangos has yet to begin. When the Board begins the collection of assessments on the imports of frozen mangos, the Board will develop a sound marketing strategy to promote frozen mangos that must be approved by USDA. In addition, when the two new importers of frozen mangos and one foreign frozen mango processor members of the Board have been seated, they too can participate in the development of the budget for research and marketing strategies for both frozen and fresh mangos.

One commenter stated that though the proposal clarified that three new seats would be added to the Board's membership—two for frozen importers and one for a frozen processor—it did not make clear to what extent these entities could be involved in both the fresh mango production and frozen mango processing. The two additional seats for importers of frozen mango can be filled by a person who imports fresh and frozen mangos as long as they meet

the requirements as discussed in the Nomination and Appointments section of this final rule. Also, for the additional seat of the foreign processor of frozen mangos, a person can be nominated for both the foreign processor of frozen mangos and foreign producer of fresh mango positions. For example, an individual can be nominated for a frozen importer seat, if the individual had imported 200,000 pounds or more of frozen mangos in a year. The same individual could also submit their name to the Board for a fresh importer seat, if they imported 500,000 or more of fresh mangos.

As stated in the Nomination and Appointment section of the proposal, the Board staff will solicit the names of frozen mango importers who import 200,000 pounds or more of frozen mangos annually for a frozen mango importer seat and the voting will be conducted by mail ballot. For the mail ballot, all eligible frozen mango importers will have the opportunity to vote for the candidates who are nominated for the two importer of frozen mango seats on the Board. For the foreign mango processor seat, nomination of the foreign processor for the frozen mangos seat will be solicited from foreign mango organizations and foreign processors. The Board staff will submit the names to the Secretary for selection of appointment. The candidate will only be selected for one seat on the Board. The candidate must be a member of the industry sector that they were appointed by the Secretary to represent.

The same commenter stated the Board membership revision should clarify whether the Board can be comprised of more than one individual from the same or sister entities on behalf of fresh or the frozen operations. The current program allows for members to serve on the Board from the same business entity or related entity for fresh mangos. The same can be afforded to the frozen mango seats if the candidates meet the qualification requirements outlined in the Nomination and Appointments section of the proposed rule.

Also, the same commenter stated it is in the best interest of the entire mango industry to have more marketing support for frozen mangos than fresh to increase demand. It is the commenter's opinion that this will generate higher overall value that will benefit mango growers, as well as both the fresh and frozen mango business. The allocation of the Board revenues will be the decision of the Board membership that would consist of both frozen and fresh mango industry stakeholders. The Board's annual budget recommendation will be submitted to USDA for approval.

Comments With No Position

One commenter wanted a clarification of a statement written in the Regulatory Flexibility Act section that reads as follows: "According to the Board, there are five first handlers of fresh mangos. Based on 2016 assessment data, the majority of first handlers handled less than \$7.5 million worth of fresh mangos and would thus be considered small entities." The same commenter stated the above could imply two scenarios, and the commenter is unsure which scenario is correct. Scenario (i): There are five first handlers of fresh mangos, most of which are small (handled less than \$7.5 million worth of mangos in 2016). Scenario (ii): Because the majority of worldwide first handlers are small, the AMS only recognizes five handlers who handled more than \$7.5 million worth of mangos in 2016. Scenario (i) correctly states the intended meaning of the quoted language from the proposed rule.

One commenter requested a 30-day comment period extension to allow the frozen mango industry sufficient time to address their concerns about the proposal. The Department granted the commenter's request for a 30-day extension. The comment period had originally closed on June 5, 2018, after a 60-day comment period, but it was extended by a notice published on June 12, 2018, that announced the 30-day comment period would end on August 13, 2018. USDA allowed interested parties a total of 90 days to comment on the proposal that was published on April 6, 2018, in the **Federal Register**.

USDA has considered all comments received and has not made any changes based on those comments.

After consideration of all relevant matters presented, including the information and recommendation submitted by the Board and other available information, it is hereby found that this rule, as hereinafter set forth, is consistent with and will effectuate the purposes of the 1996 Act.

As stated previously, section 518(d) of the 1996 Act states that the Secretary may conduct a referendum at any time to determine whether the continuation, suspension, or termination or the order or a provision of a program is favored by persons eligible to vote under that program. Once this final rule becomes effective, USDA will conduct a referendum to allow importers and handlers of fresh mangos and importers of frozen mangos to vote on whether they approve of the continuation of the program with the inclusion of frozen mangos. The results of the referendum will be published in a press release.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Mango promotion, Reporting and recording requirements.

For the reasons set forth in the preamble, 7 CFR part 1206 is amended as follows:

PART 1206—MANGO RESEARCH, PROMOTION, AND INFORMATION ORDER

- 1. The authority citation for part 1206 continues to read as follows:

Authority: 7 U.S.C. 7411–7425 and 7401.

- 2. Revise § 1206.2 to read as follows:

§ 1206.2 Board.

Board or National Mango Board means the administrative body established pursuant to § 1206.30, or such other name as recommended by the Board and approved by the Department.

- 3. Revise § 1206.6 to read as follows:

§ 1206.6 First handler.

First handler means any person (excluding a common or contract carrier) receiving fresh mangos from producers in a calendar year and who as owner, agent, or otherwise ships or causes mangos to be shipped as specified in this Order. This definition includes those engaged in the business of buying, selling and/or offering for sale; receiving; packing; grading; marketing; or distributing mangos in commercial quantities. The term first handler includes a producer who handles or markets mangos of the producer's own production.

- 4. Amend section 1206.8 by revising the section heading, redesignating the introductory text as paragraph (a) introductory text and paragraphs (1) and (2) as paragraphs (a)(1) and (2), respectively, and by adding paragraph (b).

The addition reads as follows:

§ 1206.8 Foreign producers and foreign processor of frozen mangos or foreign processor.

* * * * *

(b) *Foreign processor of frozen mangos or foreign processor* means any person:

(1) Who is engaged in the preparation of frozen mangos for market to the United States and/or who owns or shares the ownership and risk of loss of such mangos; and

(2) Who exports frozen mangos to the United States.

- 5. Revise § 1206.9 to read as follows:

§ 1206.9 Importer.

Importer means any person importing mangos into the United States in a calendar year as a principal or as an agent, broker, or consignee of any person who produces or handles mangos outside of the United States for sale in the United States, and who is listed as the importer of record for such mangos.

■ 6. Revise § 1206.11 to read as follows:

§ 1206.11 Mangos.

Mangos means the fruit of *Mangifera indica* L. of the family *Anacardiaceae*. For purposes of this Order, the term mangos includes:

- (a) *Fresh mangos*, which means mangos in their fresh form; and
- (b) *Frozen mangos*, which means mangos that are uncooked or cooked by steaming or boiling in water, and then frozen, whether or not containing added sugar or other sweetening agent.

■ 7. Revise the undesignated center heading preceding § 1206.30, and in § 1206.30, revise paragraphs (a) and (b) to read as follows:

National Mango Board

§ 1206.30 Establishment and membership.

(a) *Establishment of the National Mango Board.* There is hereby established a National Mango Board composed of eight importers of fresh mangos; one first handler of fresh mangos; two domestic producers of fresh mangos; seven foreign producers of fresh mangos; two importers of frozen mangos; and one foreign processor of frozen mangos. First handler Board members must receive 500,000 pounds or more of fresh mangos annually from producers, and importer Board members must import 500,000 pounds or more of fresh mangos or 200,000 pounds or more of frozen mangos annually. The chairperson shall reside in the United States and the Board office shall also be located in the United States.

(b) *Importer districts.* Board seats for importers of fresh mangos shall be allocated based on the volume of fresh mangos imported into the Customs Districts identified by their name and Code Number as defined in the Harmonized Tariff Schedule of the United States. Two seats shall be allocated for District I, three seats for District II, two seats for District III, and one seat for District IV. Two at-large seats shall be allocated for importers of frozen mangos who import into any of the four defined districts.

* * * * *

■ 9. In § 1206.31, revise paragraph (e), redesignate paragraph (h) as paragraph

(k), add new paragraph (h), and add paragraphs (i) and (j).

The revision and additions read as follows:

§ 1206.31 Nominations and appointments.

* * * * *

(e) Nominees to fill the fresh mango importer positions on the Board shall be solicited from all known importers of fresh mangos. The members from each district shall select the nominees for two positions on the Board. Two nominees shall be submitted for each position. The nominees shall be placed on a ballot which will be sent to fresh mango importers in the districts for a vote. For each position, the nominee receiving the highest number of votes and the nominee receiving the second highest number of votes shall be submitted to the Department as the fresh importers' first and second choice nominees.

* * * * *

(h) Nominees to fill the foreign processor of frozen mangos position on the Board shall be solicited from foreign mango organizations and from foreign processors. Foreign mango organizations shall submit two nominees for each position, and foreign processors may submit their name or the names of other foreign processors directly to the Board. The nominees shall represent the major countries exporting frozen mangos to the United States.

(i) Nominees to fill the at-large positions on the Board shall be solicited from all known importers of frozen mangos. The members from each district shall select the nominees for the two at-large positions on the Board. Two nominees shall be submitted for each position. The nominees shall be placed on a ballot which will be sent to importers of frozen mangos in each of the four districts for a vote. For each position, the nominee receiving the highest number of votes and the nominee receiving the second highest number of votes shall be submitted to the Department as the first and second choice nominees.

(j) First handler nominees must receive 500,000 pounds or more of fresh mangos annually from producers, and importer nominees must import 500,000 pounds or more of fresh mangos or 200,000 pounds or more of frozen mangos annually.

* * * * *

■ 10. Revise § 1206.32 to read as follows:

§ 1206.32 Term of office.

The term of office for first handler, importer, domestic producer, and foreign producer and foreign processor

members of the Board will be three years. Members may serve a maximum of two consecutive three-year terms. Each term of office will end on December 31, with new terms of office beginning on January 1.

■ 11. In § 1206.34, revise paragraph (a) to read as follows:

§ 1206.34 Procedure.

(a) At a Board meeting, it will be considered a quorum when at least eleven voting members are present.

* * * * *

■ 12. In § 1206.42, revise paragraphs (b) and (d)(1) through (3) and add paragraph (d)(4) to read as follows:

§ 1206.42 Assessments.

* * * * *

(b) The assessment rate on all fresh mangos shall be three quarters of a cent (\$0.0075) per pound (or \$0.0165 per kg). The assessment rate on all frozen mangos shall be one cent (\$0.01) per pound (or \$0.022 per kg). The assessment rates will be reviewed periodically and may be modified by the Board with the approval of the Department.

* * * * *

(d) * * *

(1) The assessment rate for imported fresh mangos that are identified by the numbers 0804.50.4045, 0804.50.4055, 0804.50.6045, and 0804.50.6055 in the Harmonized Tariff Schedule (HTS) of the United States shall be the same or equivalent to the rate for mangos produced in the United States.

(2) The import assessment shall be uniformly applied to imported frozen mangos that are identified by the numbers 0811.90.5200 in the Harmonized Tariff Schedule (HTS) of the United States shall be the same or equivalent to the rate for mangos produced in the United States.

(3) In the event that any HTS number subject to assessment is changed and such change is merely a replacement of a previous number and has no impact on the description of fresh mango and frozen mangos, assessments will continue to be collected based on the new numbers.

(4) The assessments due on imported mangos shall be paid when they enter or are withdrawn for consumption in the United States.

* * * * *

■ 13. In § 1206.43, revise paragraphs (a) and (b) to read as follows:

§ 1206.43 Exemptions.

(a) Any first handler of less than 500,000 pounds of fresh mangos per calendar year, or importer of less than

500,000 pounds of fresh mangos or less than 200,000 pounds of frozen mangos per calendar year may claim an exemption from the assessments required under § 1206.42. First handlers who export mangos from the United States may annually claim an exemption from the assessments required under § 1206.42.

(b) A first handler or importer desiring an exemption shall apply to the Board, on a form provided by the Board, for a certificate of exemption. A first handler must certify that it will receive less than 500,000 pounds of domestic fresh mangos during the fiscal period for which the exemption is claimed. An importer must certify that it will import less than 500,000 pounds of fresh mangos or less than 200,000 pounds of frozen mangos for the fiscal period for which the exemption is claimed.

* * * * *

■ 14. Revise § 1206.78 to read as follows:

§ 1206.78 OMB control number.

The control numbers assigned to the information collection requirements of this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, are OMB control number 0505-0001 and OMB control number 0581-0093.

■ 15. In § 1206.101, revise paragraphs (c), (d), and (e) to read as follows:

§ 1206.101 Definitions.

* * * * *

(c) *Eligible first handler* means any person, (excluding a common or contract carrier), receiving 500,000 or more pounds of fresh mangos from producers in a calendar year and who as owner, agent, or otherwise ships or causes mangos to be shipped as specified in this Order. This definition includes those engaged in the business of buying, selling and/or offering for sale; receiving; packing; grading; marketing; or distributing mangos in commercial quantities. The term first handler includes a producer who handles or markets mangos of the producer's own production.

(d) *Eligible importer* means any person importing 500,000 or more pounds of fresh mangos or 200,000 or more pounds of frozen mango into the United States in a calendar year as a principal or as an agent, broker, or consignee of any person who produces or handles mangos outside of the United States for sale in the United States, and who is listed as the importer of record for such mangos that are identified in the Harmonized Tariff Schedule of the

United States by the numbers 0804.50.4045, 0804.50.4055, 0804.50.6045, 0804.50.6055, and 0811.90.5200, during the representative period. Importation occurs when mangos originating outside of the United States are released from custody by Customs and introduced into the stream of commerce in the United States. Included are persons who hold title to foreign-produced mangos immediately upon release by Customs, as well as any persons who act on behalf of others, as agents or brokers, to secure the release of mangos from Customs when such mangos are entered or withdrawn for consumption in the United States.

(e) *Mangos* means the fruit of *Mangifera indica L.* of the family *Anacardiaceae*. The term mangos includes:

(1) *Fresh mangos*, which means in their fresh form; and

(2) *Frozen mangos*, which means mangos that are uncooked or cooked by steaming or boiling in water, and then frozen, whether or not containing added sugar or other sweetening agent.

* * * * *

Dated: February 14, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019-02859 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-02-P

DEPARTMENT OF ENERGY

10 CFR Part 430

[EERE-2012-BT-TP-0013; EERE-2014-BT-TP-0014]

RIN 1904-AC71; 1904-AD22

Energy Conservation Program: Test Procedures for Cooking Products and Test Procedures for Portable Air Conditioners; Corrections

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

ACTION: Correcting amendments.

SUMMARY: The U.S. Department of Energy (DOE) published two final rules on June 1, 2016 and December 16, 2016 amending the test procedures for portable air conditioners and cooking products, respectfully. This correction republishes amendments from both rulemakings that could not be incorporated into the Code of Federal Regulations (CFR) due to inaccurate amendatory instructions. Neither the errors nor the corrections in this document affect the substance of these

rulemakings or any of the conclusions reached in support of those rules.

DATES: This correction is effective February 21, 2019. The incorporation by reference of certain publications listed in this rule was approved by the Director of the Federal Register as of February 7, 2011 and July 1, 2016.

FOR FURTHER INFORMATION CONTACT: Appliance Standards Questions, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-2J, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-1943. Email: ApplianceStandardsQuestions@ee.doe.gov.

Ms. Celia Sher, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW, Washington, DC 20585-0121. Telephone: (202) 287-6122. Email: Celia.Sher@hq.doe.gov.

SUPPLEMENTARY INFORMATION: DOE published a final rule in the **Federal Register** on June 1, 2016, amending the test procedures for portable air conditioners. 81 FR 35242 DOE also published a final rule on December 16, 2016, amending the test procedures for cooking products. 81 FR 91418. This correction republishes amendments from both rulemakings that were not incorporated into the Code of Federal Regulations (CFR) due to inaccurate amendatory instructions. In the June 1, 2016 rule, which became effective on July 1, 2016, DOE amended 10 CFR 430.3, by adding paragraph (i)(8), addressing portable air conditioners. This amendment was inadvertently omitted from the CFR due to an inaccurate amendatory instruction. In the December 16, 2016 final rule, which became effective January 17, 2017, DOE also amended 10 CFR 430.3(i). The amendatory instruction for this amendment referred to paragraph renumbering in 10 CFR 430.3 that affected amendments previously established by another final rule which published on December 13, 2016, addressing residential dishwasher energy conservation standards. 81 FR 90072. This final rule correction specifies the amendments to 10 CFR 430.3(i) that were established in the June 1, 2016 portable air conditioners and December 16, 2016 cooking products test procedure final rules, referencing the revised paragraph numbering in the CFR. Additionally, in the December 16, 2016 rule, DOE redesignated paragraphs (l) through (u) as (m) through (v) incorrectly in the amendatory instruction. Specifically,

this document corrects 10 CFR 430.3(i) and 10 CFR 430.3(q) and (p).

Procedural Issues and Regulatory Review

The regulatory reviews conducted for this rulemaking are those set forth in the June 1, 2016 and December 16, 2016 final rules that originally codified the amendments to DOE's test procedures for portable air conditioners and cooking products. The amendments in the June 1, 2016 rulemaking became effective July 1, 2016 and the December 16, 2016 final rule amendments became effective January 17, 2017.

Pursuant to the Administrative Procedure Act, 5 U.S.C. 553(b), DOE has determined that notice and prior opportunity for comment on this rule are unnecessary and contrary to the public interest. Neither the errors nor the corrections in this document affect the substance of the rulemakings or any of the conclusions reached in support of the final rule. For these reasons, DOE has also determined that there is good cause to waive the 30-day delay in effective date.

List of Subjects in 10 CFR Part 430

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Incorporation by reference, Intergovernmental relations, Small businesses.

Signed in Washington, DC, on February 11, 2019.

Steven Chalk,

Acting Deputy Assistant Secretary for Energy Efficiency and Renewable Energy.

For the reasons set forth in the preamble, DOE amends part 430 of title 10 of the Code of Federal Regulations by making the following correcting amendments:

PART 430—ENERGY CONSERVATION PROGRAM FOR CONSUMER PRODUCTS

■ 1. The authority citation for part 430 continues to read as follows:

Authority: 42 U.S.C. 6291–6309; 28 U.S.C. 2461 note.

■ 2. Section 430.3 amended by:
 ■ a. Revising paragraph (i); and
 ■ b. Redesignating paragraphs (q) and (p) as paragraphs (p) and (q), respectively.

The revision reads as follows:

§ 430.3 Materials incorporated by reference.

* * * * *

(i) *AHAM*. Association of Home Appliance Manufacturers, 1111 19th

Street NW, Suite 402, Washington, DC 20036, 202–872–5955, or go to <http://www.aham.org>.

(1) ANSI/AHAM DH–1–2008 (“ANSI/AHAM DH–1”), Dehumidifiers, ANSI approved May 9, 2008, IBR approved for appendices X and X1 to subpart B of this part.

(2) ANSI/AHAM DW–1–2010, Household Electric Dishwashers, (ANSI approved September 18, 2010), IBR approved for appendix C1 to subpart B of this part.

(3) AHAM HLD–1–2009 (“AHAM HLD–1”), Household Tumble Type Clothes Dryers, (2009), IBR approved for appendices D1 and D2 to subpart B of this part.

(4) AHAM HRF–1–2008, (“HRF–1–2008”), Association of Home Appliance Manufacturers, Energy and Internal Volume of Refrigerating Appliances (2008), including Errata to Energy and Internal Volume of Refrigerating Appliances, Correction Sheet issued November 17, 2009, IBR approved for appendices A and B to subpart B of this part.

(5) ANSI/AHAM PAC–1–2015, (“ANSI/AHAM PAC–1–2015”), Portable Air Conditioners, June 19, 2015, IBR approved for appendix CC to subpart B of this part.

(6) ANSI/AHAM RAC–1–2008 (“ANSI/AHAM RAC–1”), Room Air Conditioners, (2008; ANSI approved July 7, 2008), IBR approved for appendix F to subpart B of this part.

* * * * *

[FR Doc. 2019–02973 Filed 2–20–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 903

RIN 1901–AB49

Administrative Updates to Personnel References

AGENCY: Office of Electricity, U.S. Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (“DOE”) publishes this final rule to update personnel references to correspond with the Secretary’s delegation of authority. This final rule is needed to reflect changes to the Secretary’s delegation of authority and does not otherwise substantively change the current regulations.

DATES: This rule is effective February 21, 2019.

FOR FURTHER INFORMATION CONTACT: Mr. Lawrence Mansueti, U.S. Department of Energy, Office of Electricity, OE–20,

1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: Lawrence.Mansueti@hq.doe.gov; Ms. Sarah Butler, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–1777. Email: sarah.butler@hq.doe.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Background and Summary of Final Rule	
II. Final Rulemaking	
III. Regulatory Review	
A. Review Under Executive Order 12866	
B. Review Under Executive Orders 13771 and 13777	
C. Review Under the National Environmental Policy Act of 1969	
D. Review Under the Regulatory Flexibility Act	
E. Review Under the Paperwork Reduction Act of 1995	
F. Review Under the Unfunded Mandates Reform Act of 1995	
G. Review Under the Treasury and General Government Appropriations Act, 1999	
H. Review Under Executive Order 13132	
I. Review Under Executive Order 12988	
J. Review Under the Treasury and General Government Appropriations Act, 2001	
K. Review Under Executive Order 13211	
L. Congressional Notification	
IV. Approval of the Office of the Secretary	

I. Background and Summary of Final Rule

The authority to confirm, approve, and place into effect interim power and transmission rates for the power marketing administrations has been delegated by the Secretary through various DOE Orders. *See* DOE Delegation Order No. 0204–33 (43 FR 60636 (Jan. 1, 1979), as amended Mar. 19, 1981) and Delegation Order No. 0204–108 (Dec. 14, 1983 (48 FR 55664), as amended 51 FR 19744 (May 30, 1986), 56 FR 41835 (Aug. 23, 1991), and 58 FR 59716 (Nov. 10, 1993)). Most recently, the Secretary delegated this authority to the Under Secretary of Energy. *See* DOE Delegation Order No. 00–002.00Q (Nov. 1, 2018). The administrative updates to personnel references in this final rule are needed to make the procedures for public participation in power and transmission rate adjustments and extensions at 10 CFR part 903 consistent with the Secretary’s delegations of authority and the amended language will allow for future changes in delegations of authority. Specifically, this final rule revises DOE regulations at 10 CFR part 903 by changing certain references to “Deputy Secretary” to “the Secretary or his or her designee.” This final rule also makes corresponding changes to the

definitions section at 10 CFR 903.2 by adding the definition of “Secretary” and removing the definition of “Deputy Secretary.”

II. Final Rulemaking

In accordance with the Administrative Procedure Act’s provisions at 5 U.S.C. 553(b), DOE generally publishes a rule in a proposed form and solicits public comment on it before issuing the rule in final. However, 5 U.S.C. 553(b)(B) provides an exception to the public comment requirement if the agency finds good cause to omit advance notice and public participation. Good cause is shown when public comment is “impracticable, unnecessary, or contrary to the public interest.”

For the aforementioned administrative updates, DOE finds that providing an opportunity for public comment prior to publication of this rule is not necessary because DOE is carrying out an administrative change that does not substantively alter the existing 10 CFR part 903 regulatory framework. For the same reason, DOE is waiving the 30-day delay in effective date.

III. Regulatory Review

A. Review Under Executive Order 12866

This final rule has been determined not to be a “significant regulatory action” under section 3(f) of Executive Order 12866, “Regulatory Planning and Review,” 58 FR 51735 (Oct. 4, 1993). Accordingly, this action was not subject to review under that Executive Order by the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB).

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs.” That Order stated that the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. The Order stated that it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations.

Additionally, on February 24, 2017, the President issued Executive Order 13777, “Enforcing the Regulatory Reform Agenda.” The Order required the head of each agency to designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform

initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

- (i) Eliminate jobs, or inhibit job creation;
- (ii) Are outdated, unnecessary, or ineffective;
- (iii) Impose costs that exceed benefits;
- (iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;
- (v) Are inconsistent with the requirements of the Information Quality Act, or the guidance issued pursuant to that Act, particularly those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard for reproducibility; or
- (vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE concludes that this final rule is consistent with the directives set forth in these executive orders. This final rule does not substantively change the existing regulations and is intended only to make personnel references in the regulations at 10 CFR part 903 consistent with the Secretary’s delegation of authority.

C. Review Under the National Environmental Policy Act of 1969

DOE has determined that this final rule is covered under the Categorical Exclusion found in DOE’s National Environmental Policy Act regulations at paragraph A.5 of appendix A to subpart D, 10 CFR part 1021, which applies to a rulemaking that amends an existing rule or regulation and that does not change the environmental effect of the rule or regulation being amended. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

D. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant

economic impact on a substantial number of small entities. As required by Executive Order 13272, “Proper Consideration of Small Entities in Agency Rulemaking,” 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel’s website: <http://energy.gov/gc/office-general-counsel>. As discussed above, DOE has determined that prior notice and opportunity for public comment is unnecessary for this final rule. In accordance with 5 U.S.C. 604(a), no regulatory flexibility analysis has been prepared for this rule.

E. Review Under the Paperwork Reduction Act of 1995

This final rule imposes no new information collection requirements subject to the Paperwork Reduction Act.

F. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. 2 U.S.C. 1532(a), (b). UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed “significant intergovernmental mandate,” and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; available at: https://www.energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf.

UMRA sections 202 and 205 do not apply to this action because they apply only to rules for which a general notice

of proposed rulemaking is published. Nevertheless, DOE has determined that this final rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of \$100 million or more in any year.

G. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277), requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. This final rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

H. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE has examined this rule and has determined that it would not preempt State law and 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. No further action is required by Executive Order 13132.

I. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write

regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note), provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule or regulation, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor

order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This final rule is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will submit to Congress a report regarding the issuance of this final rule prior to the effective date set forth at the outset of this rulemaking. The report will state that it has been determined that the rule is not a "major rule" as defined by 5 U.S.C. 801(2).

IV. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 10 CFR Part 903

Electric power rates.

Signed in Washington, DC, on February 12, 2019.

Bruce J. Walker,

Assistant Secretary, Office of Electricity.

For the reasons stated in the preamble, DOE amends part 903 of chapter III of title 10 of the Code of Federal Regulations as set forth below:

PART 903—POWER AND TRANSMISSION RATES

■ 1. The authority citation for part 903 continues to read as follows:

Authority: Secs. 301(b), 302(a), and 644 of the Department of Energy Organization Act, Pub. L. 95-91 (42 U.S.C. 7101 *et seq.*); sec. 5 of the Flood Control Act of 1944 (16 U.S.C. 825s); the Reclamation Act of 1902 (43 U.S.C. 372 *et seq.*), as amended and supplemented by subsequent enactments, particularly sec. 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and the Acts specifically applicable to individual projects or power systems.

§ 903.1 [Amended]

■ 2. Section 903.1(a) is amended by:

- a. Removing the words “Deputy Secretary of the Department of Energy” and adding in their place the words “Secretary or his or her designee”.
- b. Removing the words “Deputy Secretary” and adding in their place the words “Secretary or his or her designee”.
- 3. Section 903.2 is amended by:
 - a. Removing paragraph (c).
 - b. Redesignating paragraphs (d) through (n) as paragraphs (c) through (m);
 - c. In newly redesignated paragraph (j), removing the words “Deputy Secretary” and adding in their place the words “Secretary or his or her designee”; and
 - d. Adding a new paragraph (n).

The addition reads as follows:

§ 903.2 Definitions.

* * * * *

(n) *Secretary* means the Secretary of the United States Department of Energy.

* * * * *

§ 903.21 [Amended]

- 4. Section 903.21 is amended by:
 - a. In paragraphs (a) and (b), removing the words “Deputy Secretary’s” and adding in their place the words “Secretary’s or his or her designee’s”.
 - b. In paragraphs (b), (c), and (d), removing the words “Deputy Secretary” and adding in their place the words “Secretary or his or her designee”.

§ 903.22 [Amended]

- 5. Section 903.22(b), (d), and (h) is amended by removing the words “Deputy Secretary” and adding in their place the words “Secretary or his or her designee”.

§ 903.23 [Amended]

- 6. Section 903.23(a)(3) and (b) is amended by removing the words “Deputy Secretary” and adding in their place the words “Secretary or his or her designee”.

[FR Doc. 2019-02805 Filed 2-20-19; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2018-0385; Product Identifier 2018-CE-019-AD; Amendment 39-19554; AD 2019-03-02]

RIN 2120-AA64

Airworthiness Directives; Pacific Aerospace Limited Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for Pacific Aerospace Limited Model 750XL airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as an incorrect size bolt may have been used to assemble the elevator bellcrank pivot joint. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective March 28, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of March 28, 2019.

ADDRESSES: You may examine the AD docket on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0385; or in person at Docket Operations, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590.

For service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz.

You may view this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the internet at <http://www.regulations.gov> by searching for Docket No. FAA-2018-0385.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aerospace Engineer, FAA,

Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Pacific Aerospace Limited Model 750XL airplanes. The NPRM was published in the **Federal Register** on May 11, 2018 (83 FR 21951). The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by the Civil Aviation Authority (CAA), which is the aviation authority of New Zealand. The MCAI states:

It is possible that the elevator bellcrank pivot joint could be assembled with a bolt P/N AN4-20 that is a little too short, leaving threads inside the working area of the section of the joint.

The MCAI requires inspecting the elevator bellcrank pivot joint to determine the length of the bolt installed to determine if it is the proper size and taking all necessary corrective actions. The MCAI can be found in the AD docket on the internet at: <https://www.regulations.gov/document?D=FAA-2018-03850-002>.

Incorrectly sized bolts that are too short can cause damage from the threads of the bolt on the internal bore of the cross tube hinge plate, which could result in reduced control.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed except for minor editorial changes and changes to clarify the incorporation by reference of the service information. 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.

Related Service Information Under 1 CFR Part 51

We reviewed Pacific Aerospace Limited Service Bulletin PACSB/XL/097, Issue 1, dated March 12, 2018. The service information describes procedures for inspecting the elevator bellcrank pivot joint to determine if the correct bolt size is installed. If an incorrect size bolt is found, the service bulletin describes procedures for inspecting the cross tube to confirm structural integrity, taking necessary corrective actions, and replacing the incorrect size bolt with a correct sized bolt. 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 will affect 22 products of U.S. registry. We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$3,740, or \$170 per product.

In addition, we estimate that any necessary follow-on actions would take about 8 work-hours and require parts costing \$125, for a cost of \$805 per product. We have no way of determining the number of products that may need these actions.

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

Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority

because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

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 small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation 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 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.

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-2018-0385; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory 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.

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):

2019-03-02 Pacific Aerospace Limited:

Amendment 39-19554; Docket No. FAA-2018-0385; Product Identifier 2018-CE-019-AD.

(a) Effective Date

This AD becomes effective March 28, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pacific Aerospace Limited Model 750XL airplanes, all serial numbers through 215, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. We are issuing this AD to prevent damage from the threads of the bolt on the internal bore of the cross tube hinge plate, which could result in reduced control.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD:

(1) Within the next 150 hours time-in-service after March 28, 2019 (the effective date of this AD) or within the next 12 months after March 28, 2019 (the effective date of this AD), whichever occurs later, inspect the elevator bellcrank pivot joint to determine the length and the part number (P/N) of the bolt installed. Do the inspection using the Inspection Instructions, steps 1 through 3, in Pacific Aerospace Service Bulletin PACSB/XL/097, Issue 1, dated March 12, 2018.

(2) If you determine bolt, P/N AN4-20, is installed during the inspection required in paragraph (f)(1) of this AD, before further flight, take all necessary corrective actions using the Accomplishment Instructions in Pacific Aerospace Service Bulletin PACSB/XL/097, Issue 1, dated March 12, 2018.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4144; fax: (816) 329-4090; email: mike.kiesov@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer*: For any requirement in this AD to obtain corrective actions from a manufacturer, the action must instead be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the Civil Aviation Authority of New Zealand (CAA).

(h) Related Information

Refer to MCAI CAA AD DCA/750XL/28, dated March 22, 2018, for related information. You may examine the MCAI on the internet at: <https://www.regulations.gov/document?D=FAA-2018-0385-0002>.

(i) Material Incorporated by Reference

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

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

(i) Pacific Aerospace Limited Service Bulletin PACSB/XL/097, Issue 1, dated March 12, 2018.

(ii) [Reserved]

(3) For Pacific Aerospace Limited service information identified in this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; phone: +64 7843 6144; fax: +64 843 6134; email: pacific@aerospace.co.nz; internet: www.aerospace.co.nz.

(4) You may view this service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. In addition, you can access this service information on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2018-0385.

(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 Kansas City, Missouri, on February 11, 2019.

Melvin J. Johnson,

Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR-601.

[FR Doc. 2019-02916 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2018-0940; Airspace Docket No. 18-ASW-15]

RIN 2120-AA66

Amendment of Class E Airspace; Carrizo Springs, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace extending upward from 700 feet above the surface at Dimmit County Airport, Carrizo Springs, TX. This action is a result of an airspace review caused by the decommissioning of the Dimmit non-directional beacon (NDB) and the cancellation of the associated instrument procedures. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

DATES: Effective 0901 UTC, June 20, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>. FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Witucki, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5900.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class E airspace extending upward from 700 feet above the surface at Dimmit County Airport, Carrizo Springs, TX, to support instrument flight rules operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 60380; November 26, 2018) for Docket No. FAA-2018-0940 to amend the Class E airspace extending upward from 700 feet above the surface at Dimmit County Airport, Carrizo Springs, TX. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraphs 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies the Class E airspace extending upward from 700 feet above the surface within 6.5 mile radius (formerly 7.5 mile radius) of Dimmit County Airport, Carrizo Springs, TX. The geographic coordinates of the airport are also being updated to coincide with the FAA's aeronautical database.

This action is necessary due to an airspace review caused by the decommissioning of the Dimmit NDB and cancellation of the associated instrument procedures.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures," paragraph 5-6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Carrizo Springs, TX [Amended]

Carrizo Springs, Dimmit County Airport, TX (Lat. 28°31'20" N, long. 99°49'25" W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Dimmit County Airport.

Issued in Fort Worth, Texas, on February 13, 2019.

John Witucki,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2019-02841 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 807

[Docket ID: USAF-2018-HQ-0010]

RIN 0701-AA83

Sale to the Public

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of the Air Force's regulation concerning how Air Force units process requests to purchase Air Force Publications and Forms. This rule is internal and does not direct how the public requests publications or forms. The rule is also obsolete. It was originally published in the early 1990's prior to the Air Force establishing a public website (2003) that provided electronic versions of publications to the public free of charge. Therefore, this part can be removed from the CFR.

DATES: This rule is effective on February 21, 2019.

FOR FURTHER INFORMATION CONTACT: Phillip Canterbury at 202-404-2404.

SUPPLEMENTARY INFORMATION: It has been determined that publication of this CFR part removal for public comment is impracticable, unnecessary, and contrary to public interest because it is based on removing content which directs internal procedures and has been made obsolete by the development of the publication website. The Air Force Publications and Forms referenced in this part, and other internal Air Force policies are available on the Air Force's online publication site (<http://www.e-publishing.af.mil/>).

This rule is not significant under Executive Order (E.O.) 12866, Sec 3, "Regulatory Planning and Review," therefore; E.O. 13771, "Reducing Regulation and Controlling Regulatory Costs" does not apply.

List of Subjects in 32 CFR Part 807

Government publications.

PART 807—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 807 is removed.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2019-02940 Filed 2-20-19; 8:45 am]

BILLING CODE 5001-10-P

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 813

[Docket ID: USAF-2018-HQ-0009]

RIN 0701-AA86

Visual Information Documentation Program

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of the Air Force's regulation concerning the Visual Information Documentation Program. The part prescribes internal Air Force procedures and command responsibilities, and it is unnecessary.

DATES: This rule is effective on February 21, 2019.

FOR FURTHER INFORMATION CONTACT: David M. Steele, 703-692-4427.

SUPPLEMENTARY INFORMATION: It has been determined that seeking public comment on the removal of this CFR part is impracticable, unnecessary, and contrary to public interest since it is

based on removing publicly available internal Air Force policies and procedures. The Air Force internal policies and procedures are available on the Air Force's online publication site (<http://www.e-publishing.af.mil/>). The newest instructions, AFI 35-101, *Public Affairs*, dated January 12, 2016, and AFI 35-109, *Visual Information*, June 1, 2017, provide the Air Force with needed internal guidance in regards to the VI documentation program. Additionally, DoD Instructions 5040.02, *Visual Information (VI)* (<http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/504002p.pdf?ver=2018-04-23-085110-153>), and DoD Instruction 5040.07, *Visual Information (VI) Productions* (<http://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/504007p.pdf>), and CJCS Instruction 3205.01D, *Joint Combat Camera (COMCAM)* (http://www.jcs.mil/Portals/36/Documents/Library/Instructions/3205_01.pdf?ver=2016-02-05-175023-000) provide overarching guidance.

This rule is not significant under Executive Order (E.O.) 12866, "Regulatory Planning and Review," therefore, E.O. 13771, "Reducing Regulation and Controlling Regulatory Costs" does not apply.

List of Subjects in 32 CFR Part 813

Archives and records, Motion pictures.

PART 813—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 813 is removed.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2019-02947 Filed 2-20-19; 8:45 am]

BILLING CODE 5001-10-P

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 884

[Docket ID: USAF-2018-HQ-0008]

RIN 0701-AA85

Delivery of Personnel to United States Civilian Authorities for Trial

AGENCY: Department of the Air Force, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of the Air Force's regulation concerning the delivery of military personnel to U.S. civilian authorities for

criminal prosecution. The part prescribes internal Air Force procedures and command responsibilities and is unnecessary.

DATES: This rule is effective on February 21, 2019.

FOR FURTHER INFORMATION CONTACT:

Major Andrea M. Hunwick at 240-612-4829.

SUPPLEMENTARY INFORMATION: It has been determined that seeking public comment on the removal of this CFR part is impracticable, unnecessary, and contrary to public interest since it is based on removing publicly available internal Air Force policies and procedures.

The Air Force policy is available on the Air Force's online publication site (<http://www.e-publishing.af.mil/>). The pertinent internal Air Force instruction is currently numbered (AFI) 51-1001, but it is in the process of being renumbered and republished as AFI 51-205.

This rule is not significant under Executive Order (E.O.) 12866, "Regulatory Planning and Review," therefore, E.O. 13771, "Reducing Regulation and Controlling Regulatory Costs" does not apply.

List of Subjects in 32 CFR Part 884

Courts, Government employees, Intergovernmental relations, Law enforcement, Military personnel.

PART 884—[REMOVED]

■ Accordingly, by the authority of 5 U.S.C. 301, 32 CFR part 884 is removed.

Henry Williams,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2019-02944 Filed 2-20-19; 8:45 am]

BILLING CODE 5001-10-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2019-0019]

RIN 1625-AA00

Safety Zone; Pensacola Bay, Pensacola Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard establishes a temporary safety zone for the navigable waters within 100 yards from the center span of the Pensacola Bay Bridge,

Pensacola Beach, FL. This temporary safety zone is necessary to provide for the safety of life and property on these navigable waters during a bridge construction project on the waterway. Entry into or transiting in this zone is prohibited to all vessels, mariners, and persons unless specifically authorized by the Captain of the Port Sector Mobile (COTP) or a designated representative.

DATES: This rule is effective from March 6, 2019, through March 9, 2019.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2019-0019 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 on this rule, call or email Lieutenant Kyle D. Berry, Sector Mobile, Waterways Management Division, U.S. Coast Guard; telephone 251-441-5940, email Kyle.D.Berry@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port Sector Mobile
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. It is impracticable to publish an NPRM because we must establish this safety zone by March 6, 2019 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. Delaying the rule would compromise the safety measures necessary to protect life and property from possible hazards associated with the bridge construction project.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for

making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is contrary to public interest because it would delay the safety measures necessary to respond to potential safety hazards associated with this bridge construction project. Immediate action is needed to protect vessels and mariners from the safety hazards associated with the bridge construction project.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Mobile (COTP) has determined that potential hazards associated with the bridge construction project from March 6, 2019 through March 9, 2019 will be a safety concern for any vessels and persons within 100 yards of the center span of the Pensacola Bay Bridge at, Pensacola Beach, FL. This rule is needed to protect the public, mariners, and vessels from the potential hazards associated with the bridge construction project on the waterway.

IV. Discussion of the Rule

The Coast Guard is establishing a temporary safety zone encompassing the navigable waters within 100 yards of the center span of the Pensacola Bay Bridge in Pensacola, FL. The location and duration of this safety zone is intended to protect persons and vessels during the bridge construction project that will take place on this navigable waterway. No person or vessel will be permitted to enter or transit within the safety zone, unless specifically authorized by the COTP or a designated representative. Public notifications will be made to the local maritime community prior to the event through Broadcast Notice to Mariners (BNM). Mariners and other members of the public may also contact the COTP or designated representative to inquire about the safety zone by telephone at 251-441-5976.

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 protectors.

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 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.

This regulatory determination is based on the size, location, and duration of the safety zone. This temporary safety zone will only restrict navigation within 100 yards of the center span of the Pensacola Bay Bridge in Pensacola, FL for four days for power cable laying during a bridge construction project. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners (BNM) via VHF-FM marine channel 15 and 16 about the zone, and the rule allows vessels to seek permission to enter the zone.

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 rule will 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 V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

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 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.

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).

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 above.

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 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, which guides 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 a safety zone that will prohibit entry thru the Pensacola Bay Bridge at the center span and 100 yards from it for four days. It is 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 Record of Environmental Consideration (REC) 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 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: 46 U.S.C. 70034; 46 U.S.C. 70051; 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.T08–0019 to read as follows:

§ 165.T08–0019 Safety Zone; Pensacola Bay Bridge, Pensacola Beach, FL.

(a) *Location.* The following area is a safety zone: All navigable waters within 100 yards of the vicinity of the Pensacola Bay Bridge at the center span, Pensacola Beach, FL.

(b) *Enforcement period.* This section will be enforced from March 6, 2019 through March 9, 2019.

(c) *Regulations.* (1) The general regulations contained in § 165.23 of this part as well as the regulations in this section apply to the safety zone.

(2) Entry into this zone is prohibited unless authorized by the Captain of the Port Sector Mobile (COTP) or a designated representative.

(3) Persons or vessels seeking to enter into or transit through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF–FM channels 15 an16 or by telephone at 251–441–5976.(4) If permission is granted, all persons and vessels must comply with the instructions of the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public through broadcast notices to mariners of the enforcement period for the safety zone.

Dated: February 13, 2019.

M.R. McLellan,

Captain, U. S. Coast Guard, Captain of the Port Sector Mobile.

[FR Doc. 2019–02843 Filed 2–20–19; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 110131070–2626–02]

RIN 0648–XG781

Pacific Island Pelagic Fisheries; False Killer Whale Take Reduction Plan; Closure of Southern Exclusion Zone

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

ACTION: Temporary rule; area closure; request for comments.

SUMMARY: NMFS is closing the Southern Exclusion Zone (SEZ) to deep-set longline fishing for all vessels registered under the Hawaii longline limited access program, as a result of the fishery reaching the established annual trigger of two observed false killer whale mortalities or serious injuries (M&SI) in the fishery within the U.S. Exclusive Economic Zone (EEZ) around Hawaii. This action is necessary to comply with False Killer Whale Take Reduction Plan (Plan) regulations that establish the SEZ closure trigger and procedures to limit M&SI of false killer whales in the Hawaii deep-set longline fishery.

DATES: Effective February 22, 2019.

NMFS must receive comments by March 25, 2019.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2019–0005, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the

Federal e-Rulemaking Portal. Go to www.regulations.gov/
#!/docketDetail;D=NOAA-NMFS-2019-0005. Click the “Comment Now” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), attention Kevin Brindock, Protected Resources, 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: NMFS may not consider comments sent by any other method, to any other address or individual, or received after the end of the comment period. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT:

Kevin Brindock, Protected Resources, NMFS Pacific Islands Regional Office, 808–725–5146, kevin.brindock@noaa.gov; or Kristy Long, NMFS Office of Protected Resources, 206–526–4792, kristy.long@noaa.gov.

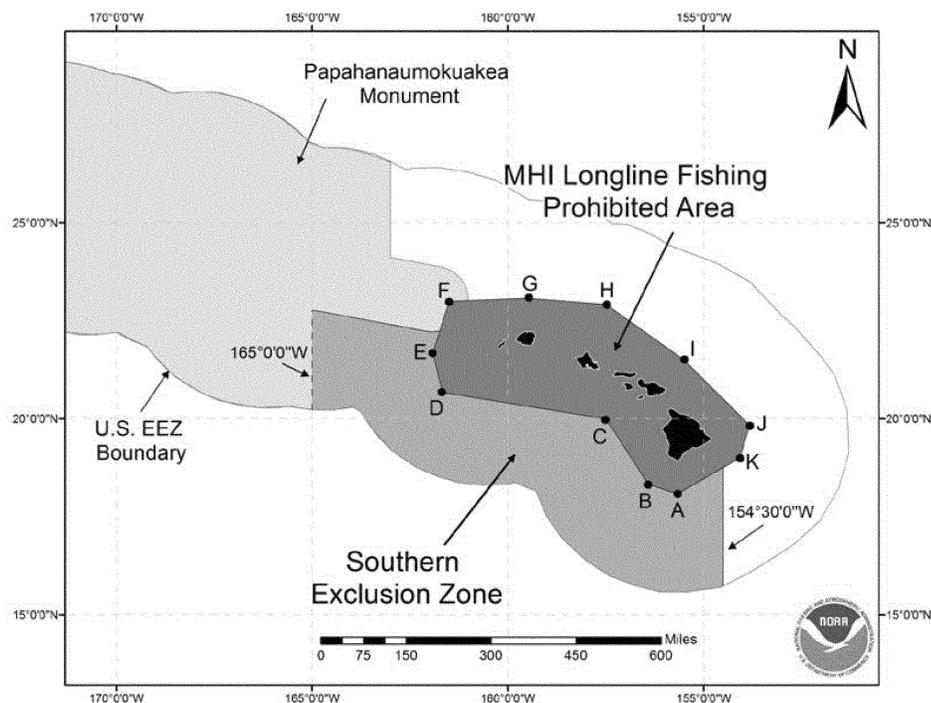
SUPPLEMENTARY INFORMATION: The False Killer Whale Take Reduction Plan (Plan) was implemented on December 31, 2012, pursuant to section 118(f) of the Marine Mammal Protection Act (MMPA) to reduce the level of incidental M&SI of the Hawaii pelagic and Hawaii insular stocks of false killer whales in the Hawaii longline fisheries (77 FR 71260; November 29, 2012). The Plan, based on consensus recommendations from the False Killer Whale Take Reduction Team, was implemented by regulations, which included the creation of the SEZ that would be closed to deep-set longline fishing if a certain number (trigger) of false killer whale M&SI are observed in the deep-set fishery in the EEZ. As described in the Plan regulations (50 CFR 229.37(d)(2)), the SEZ is bounded on the east at 154°30' W longitude, on the west at 165° W longitude, on the north by the boundaries of the Main Hawaiian Islands Longline Fishing Prohibited Area and Papahānaumokuākea Marine National Monument, and on the south by the EEZ boundary (see Fig. 1). A SEZ closure is triggered if, after expanding the number of observed M&SI, the Hawaii pelagic stock's potential biological removal

(PBR) level has been exceeded. The 2012 final rule set the trigger as the larger of either two observed M&SI of false killer whales within the EEZ around Hawaii, or the smallest number of observed M&SI of false killer whales

that, when extrapolated based on the percentage observer coverage for that year (20 percent), exceeds PBR. Under the final 2017 Stock Assessment Report, PBR is 9.3 pelagic false killer whales per year. Accordingly, with 20 percent

observer coverage, the current trigger remains two observed M&SI (*i.e.*, two observed M&SI expands to 10, which exceeds PBR of 9.3).

Figure 1. Southern Exclusion Zone.



NMFS-certified fishery observers documented two false killer whales hooked during deep-set trips in the U.S. EEZ, one each on January 10 and January 15, 2019. One of these interactions resulted in a mortality and the other animal was released injured. NMFS followed the procedures outlined in the final rule and criteria in the NMFS process for distinguishing serious from non-serious injuries of marine mammals (NMFS Policy Directive PD 02-238 and NMFS Instruction 02-238-01) to evaluate the injury of the animal that was released injured, and determined that it was a serious injury. Therefore, NMFS has determined that the SEZ trigger (*i.e.*, two M&SI) has been met, and closing the SEZ to deep-set longline fishing is required to comply with the Plan.

In accordance with 50 CFR 229.37(e)(6)), NMFS must publish notification that the SEZ will be closed to deep-set longline fishing beginning on a specified date, which is not earlier than 7 days and not later than 15 days after the date of filing the closure notice for public inspection at the Office of the Federal Register. During the closure, it

is prohibited to fish using deep-set longline gear in the SEZ.

The SEZ was closed to deep-set longline fishing on July 24, 2018, following four false killer whale serious injuries in the Hawaii deep-set longline fishery that occurred inside the EEZ around Hawaii during that calendar year. The SEZ was reopened to deep-set longline fishing on January 1, 2019. Because an observed false killer whale mortality or serious injury in the EEZ around Hawaii met the established trigger in the subsequent calendar year following an SEZ closure, the SEZ will be closed until one or more of the following criteria described in the Plan regulations (50 CFR 229.37(e)(5)) are met: (i) The Assistant Administrator determines, upon consideration of the False Killer Whale Take Reduction Team's recommendations and evaluation of all relevant circumstances, that reopening of the SEZ is warranted; (ii) In the two-year period immediately following the date of the SEZ closure, the deep-set longline fishery has zero observed false killer whale incidental mortalities and serious injuries within the remaining open areas of the EEZ

around Hawaii; (iii) In the two-year period immediately following the date of the closure, the deep-set longline fishery has reduced its total rate of false killer whale incidental mortality and serious injury (including the EEZ around Hawaii, the high seas, and the EEZ around Johnston Atoll (but not Palmyra Atoll)) by an amount equal to or greater than the rate that would be required to reduce false killer whale incidental M&SI within the EEZ around Hawaii to below the Hawaii Pelagic false killer whale stock's PBR level; or (iv) The average estimated level of false killer whale incidental M&SI in the deep-set longline fishery within the remaining open areas of the EEZ around Hawaii for up to the five most recent years is below the PBR level for the Hawaii Pelagic stock of false killer whales at that time.

This document serves as advance notification to fishermen, the fishing industry, and the general public that the SEZ will be closed to deep-set longline fishing starting on February 22, 2019.

NMFS will consider public comments on this temporary rule. NMFS must receive comments by the date provided

in the **DATES** heading, not postmarked or otherwise transmitted by this date.

Classification

There is good cause to waive prior notice and an opportunity for public comment on this action pursuant to 5 U.S.C. 553(b)(B). Providing an opportunity for prior notice and comment would be contrary to the public interest because the SEZ closure has been triggered by a second observed M&SI, and immediate closure of the SEZ is necessary to prevent additional mortalities or serious injuries, which may have unsustainable impacts on the Hawaii pelagic stock of the false killer whale. Furthermore, prior notice and comment is unnecessary because the take reduction plan final rule (77 FR 71259, November 29, 2012) that implements the procedure for closing the SEZ (codified at 50 CFR 229.37(d)(2) and (e)) has already been subject to an extensive public process, including the opportunity for prior notice and comment. All that remains is to notify the public of the second observed mortality and serious injury of a pelagic false killer whale resulting from commercial longline operations, and the longline closure of the SEZ. Although this action is being implemented without the opportunity for prior notice and comment, NMFS is soliciting and will respond to public comments from those affected by or otherwise interested in this rule.

The NOAA Assistant Administrator for Fisheries also finds good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3). Failing to waive the 30-day delay in effectiveness would likely result in additional interactions and possible M&SI to the Hawaii pelagic false killer whale stock. Under the MMPA, NMFS must reduce M&SI of marine mammal stocks protected by take reduction plan regulations. This includes taking action to close the SEZ immediately upon a second observed M&SI resulting from commercial longlining in the EEZ. Accordingly, the SEZ closure must be implemented immediately to ensure compliance with the provisions of the MMPA and the take reduction plan regulations. Nevertheless, NMFS recognizes the need for fishermen to have time to haul their gear and relocate to areas outside of the SEZ; thus, NMFS makes this action effective 7 days after filing this document in the **Federal Register**.

This action is required by 50 CFR 229.37(e)(3), and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1361 *et seq.*

Dated: February 15, 2019.

Chris Oliver,

*Assistant Administrator for Fisheries,
National Marine Fisheries Service.*

[FR Doc. 2019-02995 Filed 2-15-19; 4:15 pm]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 180212159-9102-02]

RIN 0648-BH75

Atlantic Highly Migratory Species; Shortfin Mako Shark Management Measures; Final Amendment 11

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

ACTION: Final rule.

SUMMARY: NMFS is amending the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) based on the results of the 2017 stock assessment and a subsequent binding recommendation by the International Commission for the Conservation of Atlantic Tunas (ICCAT) for North Atlantic shortfin mako sharks. The North Atlantic shortfin mako shark stock is overfished and is experiencing overfishing. Consistent with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and the Atlantic Tunas Convention Act (ATCA), NMFS is implementing management measures that will reduce fishing mortality on shortfin mako sharks and establish the foundation for rebuilding the shortfin mako shark population consistent with legal requirements. The final measures could affect U.S. commercial and recreational fishermen who target and harvest shortfin mako sharks in the Atlantic Ocean, including the Gulf of Mexico and Caribbean Sea, by increasing live releases and reducing landings. NMFS is also clarifying the definition of fork length (FL) in the definitions section of the HMS regulations.

DATES: This final rule is effective on March 3, 2019.

ADDRESSES: Copies of the Final Amendment 11 to the 2006 Consolidated HMS FMP, including the Final Environmental Impact Statement (FEIS) containing a list of references used in this document, the dusky shark stock assessments, and other documents

relevant to this rule are available from the HMS Management Division website at <https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species>.

FOR FURTHER INFORMATION CONTACT: Guý DuBeck or Karyl Brewster-Geisz at (301) 427-8503.

SUPPLEMENTARY INFORMATION:

Background

The North Atlantic shortfin mako stock is managed primarily under the authority of the Magnuson-Stevens Act and also under ATCA. The 2006 Consolidated HMS FMP and its amendments are implemented by regulations at 50 CFR part 635. A brief summary of the background of this final rule is provided below. Additional information regarding Atlantic shark management can be found in the FEIS accompanying this final rule for Amendment 11, the 2006 Consolidated HMS FMP and its amendments, the annual HMS Stock Assessment and Fishery Evaluation (SAFE) Reports, and online at <https://www.fisheries.noaa.gov/topic/atlantic-highly-migratory-species>.

The North Atlantic shortfin mako shark (*Isurus oxyrinchus*) is a highly migratory species that ranges across the entire North Atlantic Ocean and is caught by numerous countries. The stock is predominantly caught offshore in association with fisheries that primarily target tunas and tuna-like species. While these sharks are a valued component of U.S. recreational and commercial fisheries, U.S. catch represents only approximately 9 percent of the species' total catch in the North Atlantic by all reporting countries. International measures are, therefore, critical to the species' effective conservation and management.

Based on a 2017 ICCAT assessment, on December 13, 2017, NMFS issued a status determination finding the stock to be overfished and experiencing overfishing, applying domestic criteria. The 2017 assessment estimated that total North Atlantic shortfin mako catches across all ICCAT parties are currently between 3,600 and 4,750 metric tons (mt) per year. The assessment further indicated that such total catches would have to be at or below 1,000 mt (72-79 percent reductions) to prevent further population declines, and total catches of 500 mt or less would be expected to stop overfishing and begin rebuilding the stock.

Based on this information and given that the stock is primarily caught in association with ICCAT fisheries, ICCAT at its November 2017 meeting

adopted management measures for Atlantic shortfin mako in Recommendation 17–08. The measures largely focused on maximizing live releases of Atlantic shortfin mako sharks, allowing retention only in certain limited circumstances, increasing minimum size limits for retention, and improving data collection in ICCAT fisheries. ICCAT stated that the measures in the Recommendation were “expected to prevent the population from decreasing further, stop overfishing and begin to rebuild the stock.”

On March 2, 2018, NMFS implemented an interim final rule using emergency authority under the Magnuson-Stevens Act, 16 U.S.C. 1855(c), to quickly implement measures in the HMS recreational and commercial fisheries consistent with Recommendation 17–08. The emergency measures were initially effective for 180 days, and on August 22, 2018, they were extended to March 3, 2019 (83 FR 42452). This final rule is intended to replace these emergency measures with long-term measures.

A Notice of Intent (NOI) to prepare an EIS for Amendment 11 of the Consolidated HMS FMP was published in the **Federal Register** on March 5, 2018 (83 FR 9255) and provided notice of the availability of an Issues and Options document for scoping. Based on the alternatives presented and commented on during scoping, NMFS published a proposed rule for Draft Amendment 11 on July 27, 2018 (83 FR 35590), and the Environmental Protection Agency (EPA) published the notice of availability of the Draft Environmental Impact Statement (DEIS) on July 27, 2018 (83 FR 35637). The details of this rulemaking can be found in the proposed rule and are not repeated here.

During the comment period on the proposed rule and DEIS, which lasted for 73 days, NMFS conducted six public hearings (Texas, Florida, North Carolina, New Jersey, and Massachusetts) and a public webinar. In addition, NMFS presented Draft Amendment 11 to the Atlantic HMS Advisory Panel, four Atlantic Regional Fishery Management Councils (the New England, Mid-Atlantic, South Atlantic, and the Gulf of Mexico Fishery Management Councils), and the Atlantic States Marine Fisheries Commission. The comment period ended on October 8, 2018. The comments received on Draft Amendment 11 and its proposed rule, and responses to those comments, are summarized below in the section labeled “Response to Comments.”

This final rule implements the measures preferred and analyzed in the FEIS for Amendment 11 to the 2006 Consolidated HMS FMP in order to address and establish a foundation for rebuilding the North Atlantic shortfin mako shark stock, which ICCAT will adopt in 2019 after obtaining additional scientific information, as set out in Recommendation 17–08. It also includes a clarification to the regulatory definition of “FL (fork length),” as proposed and discussed in the DEIS and FEIS. The FEIS analyzed the direct, indirect, and cumulative impacts on the human environment as a result of the preferred management measures. The FEIS, including the preferred management measures, was made available on December 21, 2018 (83 FR 65670). On February 15, 2019, the Assistant Administrator for NOAA signed a Record of Decision (ROD) adopting these measures as Final Amendment 11 to the 2006 Consolidated HMS FMP. A copy of the FEIS, including Final Amendment 11 to the 2006 Consolidated HMS FMP, is available from the HMS Management Division (see **ADDRESSES**). In the FEIS, NMFS divided the alternatives into the following four broad categories for organizational clarity and to facilitate effective review: Commercial fishery, recreational fishery, monitoring, and rebuilding. NMFS fully considered 29 alternatives within these categories and is implementing five measures, one in the commercial fishery, two in the recreational fishery (each regarding a different regulation type), one regarding monitoring, and one regarding rebuilding the stock, to meet the objectives of the rule and achieve at least a 75 percent reduction in U.S. shortfin mako shark landings consistent with the suggested level of reduction recommended in the stock assessment. The stock assessment recommends this level of reduction throughout the stock’s range, and all ICCAT parties fishing on the stock are committed to take the specified measures to achieve the needed reductions. NMFS’ detailed analyses of the alternatives are provided in the FEIS for Draft Amendment 11 (see **ADDRESSES** for how to get a copy of the FEIS) and a summary is provided in the FRFA below.

In developing the final measures, NMFS considered the commercial retention restrictions and the 83-inch FL recreational minimum size limit temporarily put in place through the emergency interim final rule, public comments received on that rule, other conservation and management measures that have been implemented in the HMS

fisheries since 2008 that have affected shark fisheries or shark bycatch in other fisheries, and public comments received on the proposed rule and DEIS, including comments provided at the September 2018 HMS Advisory Panel meeting. In response to public comment on the proposed rule and the DEIS, NMFS made three changes from the proposed rule in the final rule. The first change adopts a new commercial measure that is a modified version of the previously preferred measure. A second change adopts a different recreational size limit measure that was not preferred in the proposed rule. A third change clarifies the application of retention restrictions for the few permit holders who hold a commercial shark permit and a permit that also allows recreational landings of sharks. All other proposed conservation measures, as well as the proposed clarification of the definition of “fork length,” did not change between the proposed and final rules. Measures that are different from the proposed rule, or measures that were proposed but not implemented, are described in detail in the section titles, “Changes from the Proposed Rule.”

Response to Comments

NMFS received a total of 30 individual written comments on the proposed rule from fishermen, dealers, and other interested parties along with State of North Carolina, Commonwealth of Massachusetts, the Mid-Atlantic and New England Fishery Management Councils, several shark conservation or other environmental groups, including Oceana, and several commercial and recreational groups. Oral comments were received from the South Atlantic Fishery Management Council. All written comments can be found at <http://www.regulations.gov/> by searching for RIN 0648–BH75. All of the comments received are summarized below.

Comment 1: NMFS received multiple comments expressing support for Amendment 11 management measures as well as comments opposing implementation of ICCAT shortfin mako shark recommendations. Commenters in support of Amendment 11 wanted management measures to prevent overfishing of shortfin mako sharks by placing limits and restrictions on fishing that results in mortality of shortfin mako sharks. They also stressed the need for international cooperation if shortfin mako shark measures are to be effective and the need for all countries fishing on the stock to implement comparable regulations as required by ICCAT. In addition, some commenters cited the importance of shortfin mako sharks to

the health of ocean ecosystems. One commenter opposed any management measures for shortfin mako sharks, citing their understanding of previous ICCAT stock assessment issues, including the underlying uncertainties with other shark stock assessments such as the porbeagle shark assessment. Specifically, this commenter stated that ICCAT had recommended similar regulations for porbeagle sharks after a stock assessment, and later changed the results after the United States supplied additional information.

Response: NMFS agrees that shortfin mako sharks play an important role in maintaining ocean ecosystems, and notes that there are statutory obligations to effectively manage shark fisheries, prevent overfishing, and achieve long-term sustainability of the stock. NMFS has determined that the management measures in this rule will address overfishing and begin the process of rebuilding the North Atlantic shortfin mako shark stock as required by law, understanding that any effective rebuilding plan or measures to end overfishing depend on effective international measures, given that the United States contributes to only a portion of the fishing mortality on the stock.

NMFS believes that the 2017 ICCAT stock assessment for shortfin mako sharks is not appropriately compared to the previous stock assessment for porbeagle sharks and generally does not agree with the commenter's implication that the ICCAT assessments are routinely flawed. The 2017 ICCAT stock assessment for shortfin mako sharks included many improvements in the data and modeling compared to previous shark stock assessments, including past porbeagle and shortfin mako shark assessments. NMFS has determined that the 2017 SCRS shortfin mako shark stock assessment is the best scientific information available for shortfin mako sharks, and NMFS is using the results, as appropriate, as required under National Standard 2 of the Magnuson-Stevens Act.

Comment 2: NMFS received comments about the stock assessment methodology and results. A commenter had concerns that the methodology applied in evaluating the results of different stock assessment models used in the 2017 shortfin mako stock assessment introduced an inappropriate negative bias in the overall assessment results. Other commenters were concerned about the large change in stock status between all the most recent previous ICCAT stock assessment results, the conversion rates used to convert dressed weight to whole weight

of sharks, the potential for under-reporting of harvest by other ICCAT members particularly those countries that have larger fishing fleets than the United States, and the potential implications of the Marine Recreational Information Program (MRIP) catch estimates. These commenters requested that NMFS postpone implementing Amendment 11 until the next shortfin mako shark stock assessment is completed.

Response: While there is always uncertainty in stock assessment data inputs, model outputs, and the subsequent interpretation of results, the SCRS methodologies appropriately considered how to best address such uncertainties in this particular context. The SCRS described these sources of uncertainty and concluded that the 2017 stock assessment was an improvement over previous assessments for shortfin mako sharks, and reflects the best scientific information available on the status of the stock. ICCAT reviewed and accepted the results for use in management, and made specific recommendations which the United States is obligated to implement as necessary and appropriate under ATCA. NMFS is also required to take action to end overfishing and rebuild the stock under the Magnuson-Stevens Act given the stock's status as overfished with overfishing occurring. If future stock assessments reach different conclusions regarding shortfin mako shark stock status, and changes to management measures are recommended by ICCAT, or if NMFS determines that different measures are needed to address management of the stock, then such changes may be considered at that time.

Regarding the comment expressing concern that the United States used incorrect conversion rates for dressed weight to whole weight of sharks, this issue has also come up in the context of reporting to ICCAT. As discussed with the ICCAT Advisory Committee at its Fall meeting, the United States surveyed other countries regarding the conversion rates and the manner in which those countries dress their sharks and then reviewed the data it submitted to ICCAT. Based on this review of the data and the survey of other countries' conversion factors, the United States found errors in the shortfin mako shark commercial landings data previously submitted to ICCAT and determined that changing the conversion rate to match that used by Spain and Canada was appropriate. Accordingly, the United States submitted revised estimates to ICCAT of U.S. harvest for all years. NMFS has accordingly updated all the numbers from the DEIS

in the FEIS to reflect the updated analyses, since the numbers in the DEIS were based on the ICCAT submissions. As a result of these revised estimates, the U.S. proportion of shortfin mako catches compared to all catches by all countries was reduced from 11 percent to 9 percent. For U.S. harvest, these changes also resulted in a recalculation of the relative contribution of commercial and recreational fisheries to domestic shortfin mako shark mortality. The proportion of recreational to commercial harvest is not equally split with recreational harvest accounting for 58 percent and commercial harvest (including landings and dead discards) accounting for 42 percent.

Comment 3: NMFS received comments regarding the timing and process of this rulemaking. Commenters urged NMFS to implement management measures immediately based on the best available science to rebuild the stock and end overfishing. Other commenters are concerned that this rulemaking is premature since ICCAT could make changes in upcoming meetings. Some commenters felt the United States should not act unilaterally, and implement a rebuilding plan without ICCAT. Another commenter stated that NMFS has two years to implement rebuilding plans and management measures once the stock is determined to be overfished and requested that NMFS wait to implement Amendment 11.

Response: Amendment 11 is responsive to ICCAT Recommendation 17-08, which is a binding recommendation under the ICCAT Convention, and the United States is obligated to implement it through regulations as necessary and appropriate under ATCA. Due to the requirements in Recommendation 17-08 and the status of shortfin mako sharks, NMFS worked to immediately implement the requirements in Recommendation 17-08 via an emergency interim final rule (83 FR 8946; March 2, 2018). Under sections 305(c) and 304(e)(6) of the Magnuson-Stevens Act, NMFS has the authority to implement interim measures to reduce overfishing on an emergency basis for 180 days. Those measures can be extended again for another 186 days if necessary. NMFS later extended the emergency rule for another 186 days; these emergency measures expire on March 3, 2019 (83 FR 42452; August 22, 2018). NMFS aims to have the management measures in Amendment 11 in place by the time the emergency rule expires or soon thereafter. If ICCAT changes the measures in Recommendation 17-08 at future meetings, then the United States will be

responsive to those changes, consistent with ATCA and the Magnuson-Stevens Act. NMFS does not have discretion to delay implementation of management measures adopted at ICCAT simply because we anticipate there may be additional or different ICCAT recommendations in the future. This action does not implement a unilateral rebuilding plan in U.S. waters for shortfin mako sharks. This action establishes the foundation for an international, ICCAT-recommended rebuilding plan, understanding that ICCAT intends to adopt such a plan in the future and that the United States will advocate for its development at that forum.

Regarding the comment on the two-year timeframe to implement management measures being a reason to delay implementation, we note that we have an obligation to implement the measures under ATCA and the ICCAT treaty, and that the Magnuson-Stevens Act requires NMFS to take measures to end overfishing and to rebuild the stocks. The regulatory process to amend the 2006 Consolidated HMS FMP is a lengthy process involving significant public input and review; the two-year reference in the Magnuson-Stevens Act is not to be read as a delay in starting that process, which could prevent measures from being timely implemented. Section 304(e)(6) allows for interim measures to reduce overfishing to be put in place until a FMP amendment can be finalized; this section of the Magnuson-Stevens Act only allows for these interim measures to be put in place pursuant to section 305(c), which limits the amount of time emergency measures can be effective to 366 days. Based on these regulations, NMFS published the emergency interim final rule per the authority in sections 305(c) and 304(e)(6) of the Magnuson-Stevens Act, and is implementing long-term management measures to address overfishing and establish a foundation for rebuilding shortfin mako sharks with Amendment 11, consistent with the Magnuson-Stevens Act.

Comment 4: NMFS received comments in support of adding a sunset clause to this rulemaking, which would remove regulations implemented by Amendment 11 if ICCAT makes changes to Recommendation 17–08.

Response: A “sunset clause” on regulations to address overfishing of shortfin mako sharks would not be consistent with the ICCAT recommendation, or the need to rebuild the stock, which could take decades based on the 2017 stock assessment. If ICCAT recommends changes to management measures in the future,

NMFS would implement necessary and appropriate responsive regulatory changes at that time, consistent with applicable laws.

Comment 5: NMFS received comments regarding the implementation of the ICCAT regulations and fishing operations by other countries. The commenters had concerns that other countries are not implementing the Recommendation and about the pace of the U.S. implementation when compared to other countries. Commenters also wondered if other ICCAT countries have electronic monitoring systems or observers for their fleets. In addition, the commenters believe that U.S. fishermen will be held accountable for an excessive share of the conservation burden in future ICCAT management measures.

Response: NMFS acknowledges that countries other than the United States are responsible for the majority of North Atlantic shortfin mako shark fishing mortality, hence the need for international coordination through ICCAT on measures to end overfishing and rebuild the stock. Regardless of other countries’ capability to adequately implement and enforce ICCAT recommendations, the United States remains obligated under ATCA to implement ICCAT recommendations. As a responsible party to ICCAT, NMFS will continue to work collaboratively within the ICCAT process and advocate for an effective international rebuilding plan, emphasizing the need for all parties to address their relative share of contributions to fishing mortality and for equitable management measures.

Comment 6: NMFS should implement an EFH designation for shortfin mako sharks.

Response: NMFS has recently updated EFH designations for shortfin mako sharks under Amendment 10 to the 2006 Consolidated HMS FMP. This process was initiated with the publication of the draft Atlantic HMS 5 Year Review on March 5, 2015 (80 FR 11981). In this review, NMFS identified new literature and data that should be considered in EFH delineation exercises, and recommended updating boundaries for shortfin mako sharks. There was insufficient information available per the guidelines listed at § 600.815(a)(8) to warrant a Habitat Area of Particular Concern for shortfin mako sharks. NMFS published a draft Environmental Assessment, which included proposed updates for shortfin mako shark EFH, on September 8, 2016 (81 FR 62100). NMFS received a number of written comments and comments at public meetings. Many comments included suggestions for EFH

boundaries based on academic research. NMFS completed a review of EFH-related literature in developing the FEIS (see Chapter 3 and Chapter 4 of Amendment 10 for a review of shortfin mako habitat and biology, and EFH impacts, respectively), and did not identify sufficient literature warranting changes to the recently updated EFH boundaries for shortfin mako sharks. However new data from ongoing surveys, research, and tagging programs was used to update EFH boundaries. EFH updates for shortfin mako sharks were finalized September 6, 2017 (82 FR 42329). Maps of final EFH boundaries for shortfin mako are available in Appendix G of the Final Environmental Assessment. EFH boundaries may also be viewed in the EFH Mapper, an online dynamic mapping tool maintained by the NMFS Office of Habitat Conservation (<https://www.habitat.noaa.gov/protection/efh/efhmapper/>). This office also maintains an EFH Data Inventory, which includes shapefiles of EFH boundaries that may be downloaded by the public (<https://www.habitat.noaa.gov/protection/efh/newInv/index.html>). The next 5-year review process for HMS EFH will be initiated in 2022.

Comment 7: NMFS received several comments suggesting that management measures for shortfin mako sharks should be more restrictive than those implemented in this rulemaking, including prohibiting all retention of shortfin mako sharks, or other more restrictive measures, as the science recommends.

Response: NMFS disagrees that more restrictive measures are required or necessary at this time. The management measures in Amendment 11 are consistent with those recommended in ICCAT Recommendation 17–08 and with NMFS’ obligations to address overfishing and rebuilding, understanding that the stock is fished internationally and requires international measures to effectively address these issues. The selected measures are expected to reduce U.S. shortfin mako shark catch consistent with the SCRS recommendation (72–79 percent), while still permitting fishermen to retain shortfin mako sharks under limited circumstances. Given the species’ North Atlantic-wide range and that United States catches constitute only approximately nine percent of total North Atlantic shortfin mako shark catch, the United States cannot unilaterally end overfishing and rebuild the stock through domestic regulations alone, even if there were to be a total prohibition on possession (which has not been recommended by ICCAT).

Ending overfishing and rebuilding the stock can only be accomplished through international coordination with nations that harvest the majority of shortfin mako sharks. NMFS will work with ICCAT members to evaluate the effectiveness of these measures, update stock assessment projections, establish a rebuilding plan, and develop additional measures if necessary.

Comment 8: NMFS received comments in support of the proposed preferred commercial alternative (A2), as well as other comments that suggested modifications to Alternative A2. Several commenters along with the State of Georgia and the South Atlantic and New England Fishery Management Councils supported Alternative A2 (the preferred Alternative at the proposed rule stage) since this Alternative is consistent with ICCAT Recommendation 17–08, utilized electronic monitoring, and allowed NMFS to collect real time landings and additional data. NMFS also received comments including from the State of North Carolina, Commonwealth of Massachusetts, and HMS Advisory Panel members supporting Alternative A2 with modifications. Specifically, the State of North Carolina along with other individuals suggested a modification that would allow the retention of dead shortfin mako sharks caught as bycatch in gillnet and bottom longline fisheries. The Commonwealth of Massachusetts and some HMS Advisory Panel members suggested a modification that would allow the retention of dead shortfin mako sharks by any vessel as long as there is an electronic monitoring system or an observer on board the vessel, similar to Alternative A5. These commenters also supported Alternative A3, which would allow vessels the option to opt out of the electronic monitoring system review.

Response: ICCAT Recommendation 17–08 included a variety of measures to reduce shortfin mako shark fishing mortality and to increase live releases in response to the 2017 ICCAT North Atlantic shortfin mako shark stock assessment. Among these measures was the option to require the release of shortfin mako sharks brought to the vessel alive in ICCAT fisheries. This option also allows for the retention of shortfin mako sharks in ICCAT fisheries that are dead at haulback, provided an electronic monitoring system is installed, or an observer is on board to verify the disposition of the shark. In Draft Amendment 11, NMFS preferred to implement Alternative A2, which limited the retention of dead shortfin mako sharks to those caught on vessels with an electronic monitoring system.

While the draft amendment preferred alternative did not limit the gear types that could be used to catch and retain dead shortfin mako sharks, the requirement to have an electronic monitoring system installed largely limited the measure to pelagic longline vessels since these vessels are already required to have electronic monitoring systems. Alternative A2 would satisfy the requirements of Recommendation 17–08 and also decrease fishing mortality of shortfin mako sharks. A large number of commenters expressed support for this measure. A full analysis of the ecological and socioeconomic impacts for Alternative A2 is provided in Chapter 4 of the FEIS.

However, during the public comment period, commenters that expressed support for the preferred Alternative A2 in Draft Amendment 11 also voiced support for allowing retention of dead shortfin mako sharks in other, non-ICCAT fishery gear types. Although Alternative A2 did not limit the ability to retain dead shortfin mako sharks to pelagic longline vessels, the requirement to install a costly electronic monitoring system to do so may have effectively limited the allowance for retention to the pelagic longline fishery. HMS-permitted pelagic longline vessels are already required to have electronic monitoring systems on board, but vessels using other gear types are unlikely to install the costly system in order to retain shortfin mako sharks, especially considering the relatively low ex-vessel value. Thus, the practical effect of Alternative A2 could be to limit the measure to pelagic longline vessels. To address the public comments on the Proposed Rule for Amendment 11, NMFS is implementing Alternative A7, an alternative added and analyzed in the FEIS and adopted in this final rule. Alternative A7 is a slight modification and outgrowth of Alternative A2. Under preferred Alternative A7, shortfin mako sharks caught using gillnet, bottom longline, or pelagic longline gear on properly-permitted vessels could be retained, provided they are dead at haulback. In the case of pelagic longline vessels, an electronic monitoring system would still be required, as proposed, but an electronic monitoring system would not be required on vessels that use bottom longline or gillnet gear. To be responsive to public comments, NMFS reviewed the available data for shortfin mako shark interactions by vessels that use bottom longline and gillnet gear. After reviewing the information and considering past actions, NMFS decided to add Alternative A7 as the preferred alternative. One of the alternatives in

the proposed rule analyzed and considered retention within the bottom longline and gillnet fisheries, and public comment on the alternatives resulted in the development of Alternative A7. Commenters thus could reasonably have anticipated this alternative, which is a logical outgrowth of the alternatives considered, and is consistent with the ICCAT measure's application to sharks "caught in association with ICCAT fisheries." This alternative is largely the same as Alternative A2 except that it allows retention of dead shortfin mako sharks in the bottom longline and the gillnet fisheries without requiring an observer or electronic monitoring system on board. Shortfin mako sharks are rarely caught with bottom longline and gillnet gear. Based on observer data, only 40 shortfin mako sharks were caught with bottom longline and gillnet gear from 2012 to 2017. Due to the low number of observed interactions, it is doubtful any of these landings were the result of targeted fishing so it is unlikely more could be done to avoid them. NMFS will also continue to track landings and consider additional measures if it appeared that an increase in retention results from this action, which is extremely unlikely. Retaining an additional six to seven dead sharks per year will have no additional negative effects on the stock than considered in the proposed rule, and the United States will still achieve the needed reductions in mortality with this alternative. In addition, allowing retention by these gear types will reduce regulatory dead discards in the non-ICCAT fisheries.

No other commercial gear types would be able to land shortfin mako sharks under this alternative. While it is possible for other commercial gears to catch shortfin mako sharks (*e.g.*, rod and reel and bandit gear), these gears are primarily recreational and are rarely used to fish for sharks commercially. Buoy gear in particular can interact with shortfin mako sharks but is not an authorized gear; this rule does not change that. Under this alternative, all shortfin mako sharks would need to be released if caught commercially on these other commercial gears, with the exception described below for those vessels that hold both a commercial shark permit and a permit with a shark endorsement that allows for recreational shark landings. This approach is consistent with previous rulemakings that implemented ICCAT recommendations for sharks (*e.g.*, prohibiting retention of silky, hammerhead, oceanic whitetip, or porbeagle sharks in ICCAT fisheries: 76

FR 53652, August 29, 2011; 77 FR 60632, October 4, 2012; 81 FR 57803, August 24, 2016). In those cases, NMFS applied ICCAT measures for sharks only to the pelagic longline fishery and the handgear fisheries when swordfish or tunas are retained because they are considered ICCAT fisheries for tunas and tuna-like species. NMFS consistently determined that U.S. bottom longline and gillnet vessels are not part of an ICCAT fishery because these gears do not regularly catch or land ICCAT managed species such as swordfish or tunas. In other words, Alternative A7, which would allow landings of dead shortfin mako sharks caught by these non-ICCAT fishery gear types, is consistent with past U.S. actions.

Additionally, ICCAT Recommendation 17–08 allows retention of shortfin mako sharks that are dead at haulback without the verification of electronic monitoring or observers in certain limited circumstances, including for vessels under 12 meters. Most vessels that have a Directed shark LAP and use bottom longline or gillnet gear have vessel lengths that are below 12 meters. In 2017, bottom longline vessels that interacted with sharks (based on coastal fisheries and HMS logbook reports) averaged 11.4 meters in length. In 2017, gillnet vessels that interacted with sharks (based on coastal fisheries and HMS logbook reports) averaged 9.6 meters in length. Thus, given past rulemakings and given the length of most vessels that target sharks, allowing landings of dead shortfin mako sharks by these other gear types is appropriate and consistent with ICCAT Recommendation 17–08.

Comment 9: NMFS received a suggestion for potential management measures if more commercial regulations are needed to protect the shortfin mako stock. The commenter suggested that NMFS implement a seasonal incidental limit of 18 shortfin mako sharks per trip during the summer months.

Response: The preferred alternatives in Final Amendment 11 are consistent with ICCAT Recommendation 17–08 and are designed to address the United States' contribution to the overfishing of shortfin mako sharks. If future ICCAT SCRS analyses determine that additional shortfin mako shark mortality reductions are needed, NMFS would consider other options, consistent with any ICCAT recommendations. At this time, a seasonal commercial limit of shortfin mako sharks is not consistent with ICCAT Recommendation 17–08

and it is unclear if it would achieve mortality reduction targets.

Comment 10: NMFS received a comment that the combination of preferred alternatives at the proposed rule stage, specifically Alternatives A2 and B3, would cause commercial shark permits that are held with HMS Charter/Headboat permits to be “worthless.” Such fishermen hold both permits to allow them to sell sharks caught as bycatch when fishing for tuna with handline gear. The proposed combination of alternatives would require such a dual-permitted vessel to use only pelagic longline gear, to have an electronic monitoring system, and to only land shortfin mako sharks that were greater than 83 inches fork length that were dead at haulback. These requirements would apply even when fishing on a for-hire trip.

Response: The commenter was correct that under the proposed alternatives it was unlikely that a dual-permitted vessel (which could include a variety of permits including, for example, those vessels that hold a commercial shark permit and an Atlantic Tunas General category permit that allows for retention of sharks when participating in a registered tournament) could land shortfin mako sharks. Additionally, NMFS realized this concern about permit combinations could apply to many combinations of the commercial and recreational alternatives considered. NMFS did not intend for this effect as a result of the proposed rule. As such, in the FEIS, NMFS is clarifying how the recreational limits would apply to the few individuals who hold a commercial shark vessel permit in addition to one of a variety of other vessel permits, such as HMS Charter/Headboat, that allow for recreational landings of sharks. These vessels generally fish with rod and reel or other handgear as opposed to pelagic longline, bottom longline, or gillnet gear. However, these vessels are part of the ICCAT fishery as they regularly target tunas, billfish, and swordfish. For the sake of clarity, NMFS would restrict these permit holders to the recreational shark requirements when shortfin mako sharks are onboard and prohibit them from selling any sharks when recreationally retaining shortfin mako sharks.

Comment 11: NMFS received comments both in support of and opposed to Alternative B3, which was the preferred alternative at the proposed rule stage. Some commenters, along with the Commonwealth of Massachusetts and the New England Fishery Management Council, supported Alternative B2 and management measures to protect

shortfin mako sharks until they reach maturity. These commenters generally felt that the United States strongly supported the adopted size restrictions at ICCAT, and that NMFS should not now go beyond the recommendations. These commenters noted that the same minimum size under the emergency rule reduced U.S. landings beyond the suggested reduction of 72 to 79 percent. Other commenters noted that NMFS underestimated potential reductions in landings in their analysis of the recreational alternatives because they did not account for reductions in the number of trips that would target shortfin mako sharks. The State of North Carolina supported Alternative B3 and specifically noted that if NMFS chooses Alternative B2 instead, NMFS should include shark sex identification facts on the HMS shark endorsement quiz and other outreach material. Commenters from the Gulf of Mexico supported Alternative B3 because they commonly interact with shortfin mako sharks larger than 83 inches fork length (FL). NMFS also received comments from individuals as well as the State of Georgia and the South Atlantic Fishery Management Council in support of the Alternative B3, which would establish a single recreational size limit of 83 inches FL, and is consistent with the measure established in the emergency rule. In general, these commenters felt the one size limit in Alternative B3 would remove any confusion recreational fishermen may have in identifying shortfin mako sharks by sex. Additionally, NMFS received requests for NMFS to consider other minimum sizes that are smaller than the preferred alternative of 83 inches FL. These commenters felt that NMFS should protect the larger, breeding female sharks over 83 inches FL and implement a smaller minimum size, such as 72 or 75 inches FL, for male sharks since those sharks still provide a decent amount of meat.

Response: Based on the public comment and current recreational estimated harvest under the emergency regulations (83 inches FL for all shortfin mako sharks), NMFS has decided to change the preferred alternative in the Final Amendment 11 to Alternative B2, which establishes different minimum sizes for male and female shortfin mako shark retention (71 inches FL size limit for male and 83 inches FL size limit for female shortfin mako sharks). In Draft Amendment 11 and the emergency interim final rule, the minimum size limit was increased to 83 inches FL for both males and females (Alternative B3) to significantly reduce shortfin mako

shark recreational mortality and address overfishing. One size was used for both sexes for reasons discussed in the emergency interim final rule and proposed rule. Updated data gathered from operations occurring under the emergency interim rule provisions indicate, however, that this approach would be unnecessarily restrictive for the longer term. While the shortfin mako shark landings under the 83-inch FL size limit met the suggested reduction target by weight, the size limit exceeded the target reduction in numbers of sharks harvested. As described in Chapter 4 of the FEIS, Large Pelagics Survey (LPS) data indicated there was a substantial reduction in recreational trips targeting shortfin mako sharks as a result of implementation of the emergency interim rule. The recreational landings data observed in the LPS suggest that the separate size limits for male and female sharks now preferred under Alternative B2 should still accomplish the suggested mortality reduction targets while having less detrimental economic impacts on the recreational shark fishery.

Furthermore, studies have indicated that protecting sub-adult sharks is key to conserving and rebuilding shark populations (see Chapter 4 of the FEIS). Sub-adults are generally those juvenile sharks that are a year or two away from becoming mature adults. While the now-preferred Alternative B2 will allow greater harvest of male shortfin mako sharks, those sharks will still be mature individuals as 71 inches FL is the size of maturity for male shortfin mako sharks. Given that studies have indicated that protecting sub-adult sharks is key to conserving and rebuilding shark populations, Alternative B2 ensures that sub-adults would still be adequately protected by establishing minimum size limits for male and female sharks based on their size at maturity. NMFS also anticipates that the now-preferred Alternative B2, which allows recreational fishermen the opportunity to harvest smaller male sharks, will help relieve fishing pressure on the larger female sharks, which were estimated to comprise approximately 75 percent of the harvest under the preferred alternative from the emergency interim final rule (Alternative B3), which established only one size for both males and females. Landings data from the LPS shows that female shortfin mako sharks over 83 inches FL historically made up only about 12 percent of the overall harvest. Under a single 83 inches FL size limit it is highly likely most vessels that

successfully harvest a shark over 83 inches FL will have already caught and released several smaller male sharks first. Since recreational fishermen are only allowed to harvest one shortfin mako shark per vessel per day, establishing a separate and significantly smaller size limit for male sharks will greatly increase the probability that the first legal sized shark a vessel interacts with will thus be a male shark which should lead to fewer female sharks ultimately being harvested.

Since the final preferred alternative (Alternative B2) establishes a different minimum size limit for each sex of shortfin mako shark species, NMFS intends to include information on properly distinguishing between male and female sharks on all related outreach materials, web page, and the shark endorsement video (which is mandatory for all HMS permit holders that wish to retain sharks recreationally). NMFS also expects to provide such information to registered HMS shark tournaments to make sure participants are aware of the separate size limits and how to distinguish between male and female sharks. NMFS will continue to monitor recreational landings of shortfin mako sharks, and would take action to increase the minimum size limit if recreational landings targets are not met or if enforcing separate size limits by sex proves to be impractical.

Comment 12: NMFS received a comment stating that the seasonal recreational alternatives would not allow Gulf of Mexico fishermen ample opportunity to land shortfin mako sharks since they primarily target the species outside of the months considered in the alternative.

Response: NMFS did not prefer Alternative B6, or any of its sub-alternatives, in the proposed rule due to the potential for inequitable fishing opportunities this alternative could create in terms of regional access to the shortfin mako shark recreational fishery. NMFS now prefers Alternative B2, which establishes a minimum size limit of 71 inches FL for male and 83 inches FL for female shortfin mako sharks, which would mean all recreational fishermen would have the same regulations regardless of where and when they decide to fish.

Comment 13: NMFS received comments in support of the no action recreational alternative (Alternative B1). Specifically, commenters supported keeping the shortfin mako shark recreational minimum size at status quo (54 inches FL) since they feel the population decline is not due to the recreational fishery and the recreational

fishery should not be impacted by other fisheries.

Response: While NMFS recognizes that the U.S. recreational fishery for shortfin mako sharks only makes up a small portion of the overall international harvest, its contribution to the total U.S. catch is larger than the commercial fishery landings. According to data presented in the Final Amendment 11, the U.S. recreational fishery accounts on average for 58 percent of the total U.S. catch, while the commercial fishery accounts on average for 42 percent. Therefore, U.S. recreational fisheries have a significant role to play in reducing fishing mortality on shortfin mako sharks, and must be included in management of this overfished stock. Furthermore, the no action alternative would fail to meet the minimum requirements set forth in ICCAT Recommendation 17–08 and would be inconsistent with U.S. obligations under the ICCAT treaty, ATCA, and other legal requirements.

Comment 14: NMFS received comments in support of Alternative B8, which would establish a tagging program to implement a per season limit for recreational fishermen.

Response: At this time, NMFS does not intend to implement a tagging program for recreationally harvested shortfin mako sharks since the final preferred alternative (Alternative B2) to establish minimum sizes would sufficiently reduce the recreational harvest levels. In addition, tagging programs are complicated to implement for a variety of reasons including the need to assign a limited number of tags via raffle, and the extra time and resources required to track them when reported. As discussed in the FEIS, NMFS would need to assign tags via raffle as the number of HMS permit holders with shark endorsements far exceeds the number of shortfin mako sharks that could be harvested and still meet the recommended reduction target of 72 to 79 percent. For these reasons, NMFS does not prefer a tagging program at this time.

Comment 15: NMFS received a comment suggesting that we change the shortfin mako shark recreational fishery to be similar to the bluefin tuna recreational fishery regulations. The commenter suggested a shortfin mako shark recreational fishery where permit holders would be restricted to one trophy shark over 83 inches FL, one smaller shark between 65 to 83 inches FL, and a 2 shark per season limit per recreational shark permit.

Response: The management regime suggested in this comment would be similar to the implementation of a

tagging program in that such a program would require NMFS to monitor a seasonal bag limit. Similar to the tagging program, NMFS has determined that such a management program is unnecessary to accomplish the recommended reduction in landings as the minimum size limits currently under consideration would reduce overall harvest to far fewer than two sharks per permitted vessel per season. Furthermore, a 65 inch FL size limit for shortfin mako sharks would be below the size limits stipulated in ICCAT Recommendation 17-08, and would fail to meet U.S. obligations to implement binding ICCAT recommendations under ATCA.

Comment 16: NMFS received support and opposition for the preferred alternative (Alternative B9) to implement circle hooks in the recreational fishery. Some commenters along with the Commonwealth of Massachusetts and the South Atlantic and New England Fishery Management Councils supported the preferred alternative due to the benefits of live release of sharks that may provide enhanced survivorship in some species. The State of Georgia opposed the implementation of circle hooks in the recreational fishery for sharks in federal waters due to its “questionable administration by law enforcement officers” and the unnecessary burden it will place on recreational anglers. In addition, the State of Georgia noted that it does not intend to adopt circle hooks in state waters.

Response: Research shows that the use of circle hooks reduces gut-hooking and increases post-release survival in shortfin mako sharks. French et al. (2015) examined the effects of recreational fishing techniques, including hook type, on shortfin mako sharks and found that circle hooks were more likely to hook shortfin mako sharks in the jaw compared to J-hooks. In the study, circle hooks were most likely to hook in the jaw (83 percent of the time) while J-hooks most commonly hooked in the throat (33 percent of the time) or gut (27 percent of the time). J-hooks only hooked in the jaw of shortfin mako sharks 20 percent of the time. Jaw-hooking is correlated with increased odds of post release survival. For these and other reasons (e.g., endangered species interactions), NMFS prefers this alternative. In addition, circle hooks are already required by HMS permitted commercial and recreational, except for north of 41°43' N latitude (near Chatham, Massachusetts), fishermen.

While NMFS recognizes the State of Georgia's concern regarding enforceability, circle hooks have been

required by HMS recreational permit holders since January 1, 2018, and other states, such as the State of New York, also requires the use of circle hooks when fishing for sharks. In Amendment 5b to the 2006 Consolidated HMS FMP, NMFS required the use of non-offset, non-stainless steel circle hooks by HMS recreational permit holders with a shark endorsement when fishing for sharks recreationally, except when fishing with flies or artificial lures, in federal waters south of 41°43' N latitude (near Chatham, Massachusetts). The final preferred Alternative (Alternative B9) would remove this line and require circle hooks when fishing recreationally for sharks in all areas, except when fishing with flies or artificial lures.

Comment 17: NMFS received a comment inquiring whether the new MRIP estimates would impact this rulemaking or future stock assessment.

Response: Recently, NMFS released new MRIP effort and catch estimate time series following the implementation of the new Fishing Effort Survey (FES) designed for the collection of private boat and shore-based fishing effort data, and its calibration with the data collected by the historic Coastal Household Telephone Survey (CHTS). The implications of the revised estimates on all managed species will not be fully understood for several years until they make their way through the rigorous scientific stock assessment process. In the coming years, the new and revised data will be incorporated into stock assessments at the domestic and international level as appropriate. However, NOAA Fisheries' primary source of recreational catch data for shortfin mako sharks is the Large Pelagic Survey (LPS) which does not rely on the FES, and as a result the estimates generated by the LPS used in this rulemaking have not changed.

Comment 18: NMFS received a comment stating that banning tournament fishing for sharks would help to end overfishing, and that NMFS would be justified in doing so on the grounds that tournament awards add a commercial component to what is supposed to be a recreational fishery. The commenter also stated that recreationally harvested fish should only be used for personal consumption, and not monetized.

Response: While tournaments do make up a significant portion of the recreational shark fishery, NMFS is not in favor of prohibiting shark tournaments as a means to address overfishing of shortfin mako sharks for a number of reasons. First, tournaments can provide significant economic benefits to the coastal communities in

which they are held. Second, banning tournament or sport fishing while still allowing recreational harvest would constitute an inequitable access of the resource to the problem of overfishing between tournament and non-tournament recreational fishermen, and would set a precedent that would conflict with the management of other U.S. fisheries. Retention of HMS, including shortfin mako sharks submitted for weigh-in to tournaments, is authorized under the regulations by the permitted vessel that caught the fish. Even in cases where anglers donate their fish to the tournament, the tournament is not allowed to sell the fish, but may only donate the fish for human consumption to food banks or other charities.

For HMS fisheries, most tournament participants hold recreational permits or commercial permits that only allow for recreational landings of sharks when used during a registered HMS tournament. None of these participants are allowed to sell their catch. Many commercial businesses are associated with recreational fisheries including for-hire vessels, bait and tackle shops, and fishing guides. Like tournaments, all of these operations service recreational anglers. The distinction between recreational and commercial fishing lies solely in whether the fish themselves are sold commercially, not in whether a business associated with an activity is providing a commercial service. Many shark tournaments are already moving to catch-and-release formats, or are shying away from targeting shark species that are not widely considered to be edible.

Comment 19: NMFS received support and opposition for the preferred alternative of no action Alternative C1. Some commenters along with the Commonwealth of Massachusetts, State of Georgia, and South Atlantic Fishery Management Council supported the preferred alternative since it would not add any additional reporting requirements for fishermen. However, commenters also were concerned that some registered HMS tournaments are currently not required to report their catches of all HMS. Some commenters opposed the preferred alternative since it would create inconsistency with the SCRS advice to gather more data and information on shortfin mako sharks and therefore would negatively impact science and stock assessments. Some individuals along with the Mid-Atlantic Fishery Management Council suggested that NMFS should implement mandatory reporting for all recreationally landed and discarded shortfin mako sharks. The Mid-Atlantic

Fishery Management Council stated that it is imperative to collect data from commercial and recreational fishermen on landings and discards. Other commenters would like equivalent monitoring and accountability requirements for all U.S. HMS fisheries, and to fully and accurately account for all sources of fishing mortality.

Response: There are already a number of reporting requirements under current HMS regulations for commercial and recreational fishermen fishing for shortfin mako sharks. HMS commercial fishermen report shortfin mako shark catches through vessel logbooks along with dealer reporting of landings. Under Alternative C1, HMS recreational anglers fishing from Maine to Virginia would continue to be required to report shortfin mako shark landings and releases if intercepted by the LPS, and data would continue to be collected on shortfin mako shark catches by the APIS, which is part of MRIP. As of January 1, 2019, all registered HMS tournaments will be selected for tournament reporting, which should account for a significant component of recreational shortfin mako shark landings (83 FR 63831; December 12, 2018). In addition, most for-hire vessels fishing in the federal waters in the Mid-Atlantic area (New York to New Carolina) are currently required by the Mid-Atlantic Fishery Management Council to submit electronic vessel trip reports for all their trips within 24 hours, thus providing another major data stream for shortfin mako shark landings. These current reporting systems will allow NMFS to effectively monitor the recreational harvest of the stock using a combination of traditional intercept surveys, tournament reporting, and electronic reporting making the implementation of mandatory 24-hour reporting unnecessary at this time.

NMFS understands that some constituents do not think there is equitable reporting across HMS fisheries; however, the current reporting systems mentioned above should account for all sources of fishing mortality for shortfin mako sharks. NMFS will continue to monitor the landings by commercial and recreational fishermen to determine if the current reporting systems are sufficiently accounting for shortfin mako shark mortality.

Comment 20: NMFS received a comment in support of requiring mandatory reporting with vessel monitoring systems (VMS) if it would simplify commercial fishermen's reporting burden, improve the reporting of HMS catches across all gears, and improve scientific data. The

commenters were not supportive of the alternative that would create another unnecessary burden on commercial fishermen.

Response: NMFS agrees that requiring mandatory reporting of shortfin mako sharks via VMS could potentially, and unnecessarily, increase burden to HMS commercial vessels that already report in other ways (vessel logbooks, dealer reports of landings, and electronic monitoring system) that are sufficient reporting systems for improving data collection for shortfin mako sharks. In addition, given the current reporting requirements for all HMS commercial vessels that already enable inseason monitoring and management of shortfin mako sharks, NMFS did not prefer this alternative at this time. Furthermore, NMFS is already implementing electronic HMS logbooks on a voluntary basis to improve the timeliness of reporting, and provide data for management.

Comment 21: NMFS received support and opposition for the preferred alternative. Some commenters along with the Commonwealth of Massachusetts, the State of Georgia, and the South Atlantic and Mid-Atlantic Fishery Management Councils supported the preferred alternative to develop an international rebuilding plan with ICCAT to assist with rebuilding the stock and work with other countries to implement international management measures. A commenter who opposed the preferred alternative wants NMFS to implement a domestic rebuilding plan along with the international plan, while other commenters prefer that NMFS wait until ICCAT takes further action before finalizing the rebuilding plan.

Response: North Atlantic shortfin mako shark distribution spans a large portion of the North Atlantic Ocean basin and many countries besides the United States interact with the species. Therefore, NMFS believes that addressing overfishing and preventing an overfished status can only effectively be accomplished through international efforts where other countries that have large landings of shortfin mako sharks actively and equitably participate in mortality reduction and rebuilding plan discussions. Because of the small U.S. contribution to North Atlantic shortfin mako shark mortality, domestic reductions of shortfin mako shark mortality alone would not end overfishing of the entire North Atlantic stock. For these reasons and for the reasons described in response to comment 3 above, NMFS prefers Alternative D3, which would establish the foundation for developing an

international rebuilding plan for shortfin mako sharks.

Comment 22: NMFS received a comment in support of the alternative to remove shortfin mako sharks from the pelagic shark management group and establish a separate management group with quota for the species.

Response: At this time, NMFS does not prefer a shortfin mako shark-specific quota. ICCAT Recommendation 17-08 did not include individual country allocations for shortfin mako sharks upon which to base a domestic quota. It is also not clear that a quota would adequately protect the stock by reducing mortality because quotas allow for sharks that are live at haulback to be landed. Also, it is difficult at this time to determine if setting a species-specific quota for shortfin mako sharks would have positive ecological benefits for the stock, as this scenario was not explored in the stock assessment. A species-specific quota for shortfin mako sharks would require authorized fishermen to discard all shortfin mako sharks once the quota is reached, potentially leading to an increase in regulatory discards, which would not result in decreased mortality of shortfin mako sharks and thus, contribute to the health of the stock. Additionally, commercially, shortfin mako sharks are most often caught with pelagic longline gear incidental to other target catch. Since shortfin mako sharks are rarely targeted, establishing a shortfin mako shark quota is unlikely to stop incidental fishing mortality.

NMFS believes that ending overfishing and preventing an overfished status would be better accomplished through the measures preferred in final Amendment 11 and through further critical international efforts where other countries that have large landings of shortfin mako sharks could participate in mortality reduction discussions instead of a species-specific quota within the U.S. fisheries. NMFS will continue to monitor progress in the international forum and the needs of the stock, as well as whether this action has its intended effect, and will consider whether additional measures are appropriate in the future.

Comment 23: NMFS received a comment in support of the alternative to establish bycatch caps for all fisheries that interact with shortfin mako sharks. Specifically, the commenter noted that NMFS should count the number of shortfin mako sharks caught in all fisheries, cap the number of shortfin mako sharks that can be caught, and implement accountability measures to control, track, and limit the number of

shortfin mako sharks that are killed in each fishery.

Response: At this time, NMFS does not prefer bycatch caps for all fisheries that interact with shortfin mako sharks. NMFS has reviewed all data available and found that shortfin mako sharks are primarily caught in HMS fisheries with pelagic longline gear when commercial fishermen are harvesting swordfish and tuna species, and with rod and reel gear when recreational fishermen are targeting sharks or other HMS. The species is rarely caught in other fisheries or with other gear types. To the extent they are, the final preferred commercial alternative, Alternative A7, limits any landing to shortfin mako sharks that are dead at haulback. Because shortfin mako sharks are rarely seen in fisheries other than the ones listed, establishing bycatch caps in non-pelagic longline or non-recreational handgear fisheries is unlikely to provide additional protection. As ICCAT has not established an overall TAC for shortfin mako sharks, it is difficult to determine at what level NMFS would establish a bycatch cap. Given that shortfin mako sharks are rarely caught on these other gear types, a bycatch cap would be unlikely to change fishing behavior or result in sufficient ecological benefits that compensate for administrative and regulatory burden. However, if shortfin mako shark interactions increase in those fisheries, which would then indicate fishing behavior has changed in some form, then NMFS may consider additional measures such as establishing a bycatch cap in these fisheries in the future.

Comment 24: NMFS received a comment suggesting that we increase the minimum recreational size limit for porbeagle sharks.

Response: This comment is beyond the scope of this rulemaking. The purpose of Amendment 11 is to develop and implement management measures that would address overfishing and take steps towards rebuilding the North Atlantic shortfin mako shark stock. The most recent stock assessment for porbeagle sharks indicated that the stock was overfished, but overfishing was no longer occurring, and showing signs of early rebuilding. At this time, NMFS does not have any new scientific information to justify increasing the minimum recreational size limit for porbeagle sharks.

Changes From the Proposed Rule (83 FR 35590; July 27, 2018)

This section explains the changes in the regulatory text from the proposed rule to the final rule. Some changes were made in response to public

comment, and others clarify text for the final rule. The changes from the proposed rule text in the final rule are described below.

1. § 635.20(e)(2) and (e)(6). Modification to the Recreational Minimum Size Limit for Shortfin Mako Sharks

This final rule implements separate size limits for male (71 inches FL) and female (83 inches FL) shortfin mako sharks under Alternative B2 as opposed to the single size limit of 83 inches FL (Alternative B3) that was preferred in the proposed rule and implemented in the emergency interim final rule. NMFS decided to change the preferred alternative due to public comment and updated data on the effects of the emergency interim final rule measure on estimated landings and directed effort for shortfin mako sharks in the recreational fishery. The minimum sizes in the final rule also directly match the measures in the ICCAT recommendation, which provided different minimum sizes for males and females.

For the emergency interim rule and the proposed rule, NMFS assumed in the recreational analyses that directed effort for shortfin mako sharks would not change as a result of a change in the minimum retention size, but the 2018 LPS data found that effort actually went down substantially. Thus, NMFS now understands the estimates of expected landings reductions in the earlier actions to be overly conservative. Furthermore, public comment reflected that fewer recreational trips were taken due to the larger minimum size limit and reduced likelihood of catching and landing a shortfin mako shark above the size limit. Thus, in the final rule, it is appropriate to reduce the minimum size limit for males to 71 inches FL, consistent with the ICCAT recommendation. The minimum size for female mako sharks will remain at 83 inches FL.

The differing minimum size limits in the preferred alternative are expected to achieve the needed reduction in landings and fishing mortality while protecting reproductive-age female shortfin mako sharks, but with fewer socio-economic impacts to recreational fishermen. By reducing the minimum size for retaining male shortfin mako sharks, fishermen may more frequently harvest smaller, mature male sharks instead of the larger female sharks, which will leave more female sharks that are critical to reproduction of the stock in the population. This approach, which reduces fishing pressure on the female spawning stock, is consistent with general scientific advice about

sharks. (Cortes 2002, Chapple and Botsford 2013).

According to length composition information from the LPS from 2012 through 2017, this final action would reduce the number of recreational landings of male shortfin mako sharks by up to 47 percent and female shortfin mako sharks by up to 78 percent for an average reduction in total mortality of 65 percent, if fishing effort for shortfin mako sharks were to remain the same. However, the reduction in landings under this alternative is likely to be somewhat greater than that because recreational fishermen likely will continue taking fewer trips targeting shortfin mako sharks as a result of the changes in size limits. Effort data collected via the LPS suggests that in 2018 there was a large reduction in directed fishing trips targeting shortfin mako sharks under the 83-inch FL size limit implemented by the emergency interim final rule compared to the previous six-year average. Directed trips in the LPS region (Maine to Virginia) for shortfin mako sharks from June through August 2018 declined an estimated 34 percent compared to the six-year average from 2012 through 2017. This reduction in directed trips resulted in greater than projected reductions in shortfin mako shark landings. The June through August time period traditionally accounts for over 90 percent of directed trips for shortfin mako sharks. Based on the LPS data from 2012 through 2017, shortfin mako sharks were the primary target species in approximately 67 percent of trips that caught and 75 percent of trips that landed the species. As such, a reduction in directed fishing effort could substantially reduce the landings expected under this alternative, while achieving the needed fishing mortality reductions in conjunction with other measures in the final rule.

As explained above in the comment and response section, such reductions in fishing effort should result in landings reductions that more closely result in the ICCAT reduction target of 72 to 79 percent than those that would have resulted from the single 83-inch FL size limit (Alternative B3), which resulted in greater reductions. Thus, NMFS is implementing two separate size limits for shortfin mako sharks.

Public comment reflects that some people are concerned about the ability of recreational shark anglers to differentiate between male and female sharks. NMFS is adding information on how to distinguish the sex of sharks in shark outreach materials, including the Shark Endorsement educational video that all HMS permit holders must watch

if they wish to receive a shark endorsement needed to retain sharks recreational.

2. §§ 635.21(a)(4), (c)(1), (d)(5), and (g)(6); 635.24(a)(4); and 635.71(d)(27) and (d)(28). *Modification to Authorized Commercial Gear To Retain Shortfin Mako Sharks*

The commercial measure preferred in the proposed rule (Alternative A2) only allowed the retention of shortfin mako sharks that were dead at haulback by vessels with a functioning electronic monitoring system on board the vessel. While the proposed measure did not limit the gear types that could be used to catch and retain dead shortfin mako sharks, the requirement to have an electronic monitoring system installed effectively limited the measure to pelagic longline vessels since those vessels are already required to have electronic monitoring systems. In response to public comments, NMFS reviewed the available data for shortfin mako shark interactions by vessels that use bottom longline and gillnet gear. Available data indicates that allowing fishermen to retain dead shortfin mako sharks caught in bottom longline or gillnet gear is unlikely to impact the overall mortality or harvest totals, since these gear types rarely interact with the species. Specifically, commercial shark fishermen using bottom longline or gillnet gear rarely, if ever, catch shortfin mako sharks. Since 2012, only six shortfin mako shark were observed in the bottom longline shark fishery and 34 were observed in the gillnet shark fishery. ICCAT Recommendation 17–08 allows retention of shortfin mako sharks that are dead at haulback without the verification of electronic monitoring or observers in certain limited circumstances, including for vessels under 12 meters. Most vessels that have a shark LAP and use bottom longline or gillnet gear have vessel lengths that are below 12 meters. In 2017, bottom longline vessels that interacted with sharks (based on coastal fisheries and HMS logbook reports) averaged 11.4 meters in length. In 2017, gillnet vessels that interacted with sharks (based on coastal fisheries and HMS logbook reports) averaged 9.6 meters in length. Thus, given past rulemakings and given the length of most vessels that target sharks, allowing landings of dead shortfin mako sharks by these other gear types is appropriate and consistent with ICCAT Recommendation 17–08. As a result, in the final rule, NMFS will allow for the retention of shortfin mako sharks that are dead at haulback by properly-permitted vessels that are fishing with bottom longline or gillnet

gear even if they do not have a functioning electronic monitoring system on board. The changes in the regulatory text specifies that vessels with bottom longline or gillnet gear onboard must release all live shortfin mako sharks.

3. § 635.22(c)(1) and (c)(7). *Modifications Regarding Atlantic HMS Charter/Headboat, Atlantic Tunas General Category, and Swordfish General Commercial Permit Holders*

Based on public comment, NMFS is clarifying how the recreational limits would apply to the few individuals who hold a commercial shark vessel permit in addition to one of a variety of other vessel permits, such as HMS Charter/Headboat, that allow for recreational landings of sharks under certain circumstances. These individuals generally fish with rod and reel or other handgear as opposed to pelagic longline, bottom longline, or gillnet gear. While they hold a commercial shark permit, for the most part, these individuals are fishing for sharks recreationally. However, under the combination of measures in the proposed rule, these individuals would not be allowed to land any shortfin mako sharks as they would not have the electronic monitoring equipment required under the proposed commercial measures. For the sake of clarity and in response to public comment, this rule specifies that the recreational shark requirements, including the no sale requirement, apply for these individuals when shortfin mako sharks are onboard.

Classification

Pursuant to the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the final rule is consistent with the 2006 Consolidated HMS FMP and its amendments, other provisions of the Magnuson-Stevens Act, ATCA, and other applicable law.

The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the 30-day delay in effective date under 5 U.S.C. 553(d)(3) of the Administrative Procedure Act. Delaying the effectiveness of these regulations could undermine the purpose of this action to put in place measures to address overfishing of shortfin mako sharks. Similar measures were originally implemented by emergency interim final rule under Section 305(c) of the Magnuson-Stevens Act, and have been in place for since March 2018. The emergency measures will expire on March 3, 2019, and a lapse in these measures would be confusing to the regulated community, complicate enforcement efforts, and potentially

harm the long-term sustainability of the stock. While NMFS originally timed the rulemaking to allow for a delay in effectiveness, a lapse in government appropriations resulted in a government shutdown for 35 days in December 2018–January 2019. If these measures are not implemented before the emergency rule expires, technically the management measures for the stock would revert to those that existed prior to the emergency rule. This means the recreational minimum size limit for shortfin mako sharks would revert to 54 inches FL, the use of circle hooks by recreational fishermen would not be required across the range of the species stock, and commercial fishermen would no longer be required to release shortfin mako sharks that are alive at haulback. This would be confusing for the regulated community, which would then be required to switch to the new regulations only 30 days later. In the event of a short lapse between the emergency rule and implementation of this final rule, NMFS would notify the regulated community of the situation and encourage voluntary compliance with the emergency rule measures for consistency but compliance would not be assured. Thus, the need to implement these measures in a timely manner to reduce the risk of overfishing shortfin mako sharks constitute good cause to make the rule effective immediately upon publication in the **Federal Register**. Furthermore, prior to the release of this final rule, on December 14, 2018, NMFS published a notice of availability of the Final EIS supporting this action, thereby providing the public and affected entities prior notice of the final measures contained in this rule.

This final rule has been determined to be not significant for purposes of Executive Order 12866. The Agency has consulted, to the extent practicable, with appropriate state and local officials to address the principles, criteria, and requirements of Executive Order 13132.

In compliance with section 604 of the Regulatory Flexibility Act (RFA), NMFS prepared a Final Regulatory Flexibility Analysis (FRFA) for this final rule. The FRFA analyzes the anticipated economic impacts of the final actions and any significant economic impacts on small entities. The FRFA is below.

Section 604(a)(1) of the RFA requires a succinct statement of the need for and objectives of the rule. Consistent with the provisions of the Magnuson-Stevens Act and ATCA, NMFS plans to modify the 2006 Atlantic HMS FMP in response to ICCAT Recommendation 17–08 and the stock status determination for shortfin mako sharks. NMFS has identified the following objectives with

regard to this action: Address overfishing of shortfin mako sharks; take steps towards rebuilding; establish the foundation for rebuilding the North Atlantic shortfin mako stock; and modify the 2006 Consolidated HMS FMP in response to ICCAT Recommendation 17–08 and the stock status determination for shortfin mako sharks.

Section 604(a)(2) requires a summary of significant issues raised by public comment in response to the IRFA and a summary of the assessment of the Agency of such issues, and a statement of any changes made in the rule as a result of such comments. NMFS did not receive any comments specifically on the IRFA, however the Agency did receive some comments regarding the anticipated or perceived economic impact of the rule. Summarized public comments and the Agency's responses to them are included above. We did not receive any comments from the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule or the IRFA.

Section 604(a)(4) of the Regulatory Flexibility Act requires Agencies to provide an estimate of the number of small entities to which the rule would apply. The Small Business Administration (SBA) has established size criteria for all major industry sectors in the United States, including fish harvesters. Provision is made under SBA's regulations for an agency to develop its own industry-specific size standards after consultation with SBA Office of Advocacy and an opportunity for public comment (see 13 CFR 121.903(c)). Under this provision, NMFS may establish size standards that differ from those established by the SBA Office of Size Standards, but only for use by NMFS and only for the purpose of conducting an analysis of economic effects in fulfillment of the agency's obligations under the RFA. To utilize this provision, NMFS must publish such size standards in the **Federal Register** (FR), which NMFS did on December 29, 2015 (80 FR 81194, December 29, 2015). In this final rule, effective on July 1, 2016, NMFS established a small business size standard of \$11 million in annual gross receipts for all businesses in the commercial fishing industry (NAICS 11411) for RFA compliance purposes. NMFS considers all HMS permit holders to be small entities because they had average annual receipts of less than \$11 million for commercial fishing. The Small Business Administration (SBA) has established size standards for all other major industry sectors in the U.S., including the scenic and sightseeing

transportation (water) sector (NAICS code 487210, for-hire), which includes charter/party boat entities. The Small Business Administration (SBA) has defined a small charter/party boat entity as one with average annual receipts (revenue) of less than \$7.5 million.

Regarding those entities that would be directly affected by the recreational management measures, HMS Angling (Recreational) category permits are typically obtained by individuals who are not considered businesses or small entities for purposes of the RFA because they are not engaged in commercial business activity. Vessels with the HMS Charter/Headboat category permit can operate as for-hire vessels. These permit holders can be regarded as small entities for RFA purposes (*i.e.*, they are engaged in the business of fish harvesting, are independently owned or operated, are not dominant in their field of operation, and have average annual revenues of less than \$7.5 million). Overall, the recreational alternatives would have impacts on the portion of the 3,635 HMS Charter/Headboat permit holders who hold a shark endorsement. There were also 287 registered HMS tournaments in 2017, which could be impacted by this rule. Of those registered HMS tournaments, 75 had awards or prizes for pelagic sharks.

Regarding those entities that would be directly affected by the preferred commercial management measures, the average annual revenue per active pelagic longline vessel is estimated to be \$187,000 based on the 170 active vessels between 2006 and 2012 that produced an estimated \$31.8 million in revenue annually. The maximum annual revenue for any pelagic longline vessel between 2006 and 2016 was less than \$1.9 million, well below the NMFS small business size standard for commercial fishing businesses of \$11 million. Other non-longline HMS commercial fishing vessels generally earn less revenue than pelagic longline vessels. Therefore, NMFS considers all Atlantic HMS commercial permit holders to be small entities (*i.e.*, they are engaged in the business of fish harvesting, are independently owned or operated, are not dominant in their field of operation, and have combined annual receipts not in excess of \$11 million for all its affiliated operations worldwide). The preferred commercial alternatives would apply to the 280 Atlantic tunas Longline category permit holders, 220 directed shark permit holders, and 268 incidental shark permit holders. Of these 280 permit holders, 88 pelagic longline vessels were actively fishing in 2017 based on logbook records. Based on HMS and Coastal Fisheries Logbook

data, an average of 20 vessels per year that used gear other than pelagic longline gear interacted with shortfin mako sharks between 2015 and 2017.

NMFS has determined that the preferred alternatives would not likely directly affect any small organizations or small government jurisdictions defined under RFA, nor would there be disproportionate economic impacts between large and small entities. Furthermore, there would be no disproportionate economic impacts among the universe of vessels based on gear, home port, or vessel length.

Section 604(a)(5) of the RFA requires agencies to describe any new reporting, record-keeping and other compliance requirements. The action does not contain any new collection of information, reporting, or record-keeping requirements.

Section 604(a)(6) of the RFA requires agencies to describe the steps taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected. Alternative A1, the No Action alternative, would keep the non-emergency rule regulations for shortfin mako sharks. Once the emergency rule for shortfin mako sharks expires, management measures would revert back to those effective before March 2018 (*e.g.*, no requirement to release shortfin mako sharks that are alive at haulback). Directed and incidental shark LAP holders would continue to be allowed to land and sell shortfin mako sharks to an authorized dealer, subject to current limits, including the pelagic shark commercial quota. Short-term direct economic impacts on small entities would likely be neutral since commercial fishermen could continue to catch and retain shortfin mako sharks at a similar level and rate as the status quo.

In recent years, about 181,000 lb dw of shortfin mako sharks have been landed and the commercial revenues from shortfin mako sharks have averaged approximately \$373,000 per year, which equates to approximately 1 percent of overall HMS ex-vessel revenues. Approximately 97.5 percent of shortfin mako commercial landings, based on dealer reports, were made by pelagic longline vessels. There were 88 pelagic longline vessels that were active in 2017 based on logbook reports. Therefore, the average revenue from shortfin mako shark landings per

pelagic longline vessel is \$4,133 per year.

Even though pelagic longline gear is the primary commercial gear used to land shortfin mako sharks, other gear types also interact with this species. Based on HMS and Coastal Fisheries Logbook data, an average of 20 vessels per year that used gear other than pelagic longline gear interacted with shortfin mako sharks between 2015 and 2017. Therefore, these vessels that used gear other than pelagic longline gear landed an average of only \$933 worth of shortfin mako sharks per year.

Under Alternative A2, retention of shortfin mako sharks would only be allowed if the following three criteria are met: (1) The vessel has been issued a Directed or Incidental shark LAP, (2) the shark is dead at haulback, and (3) there is a functional electronic monitoring system on board the vessel. This alternative is designed to be consistent with one of the limited provisions allowing retention of shortfin mako sharks under ICCAT Recommendation 17–08. Under the current HMS regulations, all HMS permitted vessels that fish with pelagic longline gear are already required to have a functional electronic monitoring system (79 FR 71510; December 2, 2014) and either a Directed or an Incidental shark LAP. Vessels utilizing other gear types (*i.e.*, gillnet or bottom longline) are not required to have an electronic monitoring system under current regulations but could choose to install one if the operator wishes to retain shortfin mako sharks that are dead at haulback and if the vessel holds a commercial shark LAP. Under this alternative, the electronic monitoring system would be used to verify and ensure that only shortfin mako sharks dead at haulback were retained.

This alternative would be consistent with ICCAT Recommendation 17–08 and would reduce the number of landings by pelagic longline vessels on average by 74 percent based on observer data from 2012–2017. A 74 percent reduction in shortfin mako landings would reduce revenues by an average of \$3,058 per vessel for the 88 activate pelagic longline vessels and would eliminate all of the \$933 in landing per vessel by the 10 non-pelagic longline vessels that landing shortfin mako sharks since those vessels are unlikely to have electronic monitoring systems currently installed. Those non-pelagic longline vessels would need to pay to install electronic monitoring systems if they wish to retain shortfin mako sharks, introducing an additional expense for those vessels if it there were an economic incentive for those vessels

to try to retain shortfin mako sharks under this alternative. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels. However, shortfin mako sharks are rarely a target species and are worth less than other target species. Although this alternative was preferred at the DEIS stage, NOAA Fisheries now prefers Alternative A7 which is a slightly modified version of Alternative A2. Because Alternative A7 is responsive to public comment while still meeting management goals, NOAA Fisheries no longer prefers Alternative A2.

Alternative A3 is similar to Alternative A2 except that the ability to retain dead shortfin mako sharks would be limited to permit holders that opt in to a program that would use the existing electronic monitoring systems, which are currently used in relation to the bluefin tuna IBQ program, also to verify the disposition of shortfin mako sharks at haulback. In other words, this alternative would allow for retention of shortfin mako sharks that are dead at haulback by persons with a Directed or Incidental shark LAP only if permit holders opt in to enhanced electronic monitoring coverage. If the permit holder does not opt in to the enhanced electronic monitoring coverage, they could not retain any shortfin mako sharks.

The economic impacts to small entities under this alternative are expected to be similar to those under Alternative A2. Under this alternative, a portion of the pelagic longline fleet could opt out of any retention of shortfin mako sharks, resulting in a greater reduction in overall shark ex-vessel revenue for those vessels. Overall, the socioeconomic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Non-pelagic longline vessels would need to pay to install electronic monitoring systems if they wish to retain shortfin mako sharks, introducing an additional expense for those vessels. Due to the low commercial value of shortfin mako sharks and the high cost of electronic monitoring it is reasonable to expect that these fisheries will not install cameras and therefore will not retain shortfin mako sharks. Overall, this alternative would have minor economic costs on small entities by reducing the number of shortfin mako sharks landed and sold.

Alternative A4 would establish a commercial minimum size of 83 inches FL (210 cm FL) for retention of shortfin mako sharks caught incidentally during fishing for other species, whether the shark is dead or alive at haulback. Based on observer data, only 8 percent of shortfin mako sharks are caught with pelagic longline gear greater than 83 inches FL. Thus, restricting fishermen to retaining 8 percent of shortfin mako sharks would represent a considerable reduction in number of shortfin mako sharks landed and in the resulting ex-vessel revenue. A 92 percent reduction in shortfin mako landings would reduce annual revenues by an average of \$3,802 per vessel for the 88 activate pelagic longline vessels and would reduce annual revenues by an average of \$858 per vessel for the 10 non-pelagic longline vessels that land shortfin mako sharks. However, the overall economic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (*e.g.*, bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic impacts on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species.

Alternative A5 would allow fishermen to retain shortfin mako sharks caught on any commercial gear (*e.g.*, pelagic longline, bottom longline, gillnet, handgear) provided that an observer is on board that can verify that the shark was dead at haulback. Under this alternative, electronic monitoring would not be used to verify the disposition of shortfin mako sharks caught on pelagic longline gear, but instead pelagic longline vessels could only retain shortfin mako sharks when the sharks are dead at haulback and an observer is on board.

Since only five percent of pelagic longline gear trips are observed, this alternative would result in a 95 percent reduction in the number of shortfin mako sharks retained on pelagic longline gear. A 95 percent reduction in shortfin mako landings would reduce annual revenues by an average of \$3,926 per vessel for the 88 activate pelagic longline vessels and would reduce annual revenues by an average of \$886 per vessel for the 10 non-pelagic longline vessels that land shortfin mako sharks. However, the overall economic

impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (*e.g.*, bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species. Compared to the preferred Alternative A7, this alternative would place more restrictive limits on fishermen using pelagic longline, bottom longline, and gillnet gear. Observers are only occasionally on board vessels, so limiting the retention of shortfin mako sharks to trips with an observer would reduce the opportunity to retain dead individuals. The reduced opportunity to retain dead shortfin mako sharks would not reduce fishing mortality on the stock. Therefore, NMFS does not prefer this alternative at this time.

Alternative A6 would place shortfin mako sharks on the prohibited sharks list to prohibit any catch or retention of shortfin mako sharks in commercial HMS fisheries. In recent years, about 181,000 lb dw of shortfin mako sharks have been landed and the commercial revenues from shortfin mako sharks have averaged approximately \$373,000 per year, which equates to approximately one percent of overall HMS ex-vessel revenues. That revenue would be eliminated under this alternative. Approximately 97.26 percent of shortfin mako commercial landings, based on dealer reports, were made by pelagic longline vessels. There were 88 pelagic longline vessels that were active in 2017 based on logbook reports. Therefore, the average loss in annual revenue from shortfin mako shark landings per pelagic longline vessel would be \$4,133 per year. The average loss in annual revenue from shortfin mako shark landings for vessel using other gear types would be \$933 per year. However, the overall economic impacts associated with these reductions in revenue are not expected be substantial, as shortfin mako sharks comprise less than one percent of total HMS ex-vessel revenues on average. Additionally, the magnitude of shortfin mako landings by other gear types (*e.g.*, bottom longline, gillnet, handgear) is very small. Overall, this alternative would have minor economic costs on

small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels, however, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species. Therefore, NMFS does not prefer this alternative at this time.

Based on public comment, Alternative A7 is a new alternative in this FEIS that is a logical outgrowth of the previously-preferred Alternative A2. Under preferred Alternative A7, shortfin mako sharks caught using gillnet, bottom longline, or pelagic longline gear on properly-permitted vessels could be retained, provided they are dead at haulback. In the case of pelagic longline vessels, an electronic monitoring system would be required, but not on bottom longline of gillnet vessels.

During the public comment period, some commenters that expressed support for the DEIS preferred alternative also voiced support for expanding the ability to retain dead shortfin mako sharks should not be limited solely to the pelagic longline gear, and they felt that requiring electronic monitoring systems on small vessels essentially would effectively create such a restriction. Although the DEIS preferred alternative did not limit the ability to retain dead shortfin mako sharks to pelagic longline vessels, the requirement to install a costly electronic monitoring system to do so may have limited the measure to the pelagic longline fishery. HMS-permitted pelagic longline vessels are already required to have electronic monitoring systems on board, but vessels using other gear types are unlikely to install the costly system in order to retain shortfin mako sharks, especially considering the relatively low ex-vessel value. Thus, the practical effect of Alternative A2 could be to limit the measure to pelagic longline vessels. To address the public comments, NOAA Fisheries now prefers Alternative A7, a newly added alternative in the FEIS that is a slightly modified extension of Alternative A2. Under preferred Alternative A7, shortfin mako sharks caught using gillnet, bottom longline, or pelagic longline gear on properly-permitted vessels could be retained, provided they are dead at haulback. In the case of pelagic longline vessels, an electronic monitoring system would be required, but not on bottom longline or gillnet vessels.

This alternative would have a similar impact as Alternative A2 for pelagic longline vessels (reducing revenues by an average of \$3,058 per vessel), but it would not impact the estimated 10 non-pelagic longline vessels. Therefore, it would prevent the estimated \$933 in

reduced landings per vessel for those non-pelagic longline vessels that would occur under Alternative A2. Allowing fishermen to retain dead shortfin mako sharks caught in bottom longline or gillnet gear is unlikely to have a large impact since these gear types rarely interact with the species. Overall, this alternative would have minor economic costs on small entities because these measures would reduce the number of shortfin mako sharks landed and sold by these fishing vessels. However, shortfin mako sharks are rarely a target species and are worth less than other more valuable target species. NMFS prefers this alternative because it achieves the objectives of the amendment and largely the same conservation benefit while easing costly requirements on small vessels and thus with less economic impact or restrictions on commercial fishermen.

While HMS Angling permit holders are not considered small entities by NMFS for purposes of the Regulatory Flexibility Act, Charter/Headboat permit holders and tournament operators are considered to be small entities and could be potentially impacted by the various recreational alternatives, as described below.

NMFS received public comment that indicated the proposed suite of measures presented in Alternatives B2 through B8 particularly restricted vessels with multiple HMS permits. These vessels generally fish with rod and reel or other handgear as opposed to pelagic longline, bottom longline, or gillnet gear. However, these vessels are part of the ICCAT fishery as they regularly target tunas, billfish, and swordfish. For the sake of clarity, we are therefore limiting them to the recreational shark requirements when shortfin mako sharks are onboard, and prohibiting them from selling any sharks when recreationally retaining shortfin mako sharks.

For these alternatives, a vessel issued both a Federal Atlantic commercial shark vessel permit under § 635.4(e) and an HMS Charter/Headboat permit with a shark endorsement under § 635.4(b) could land shortfin mako sharks in accordance with the recreational size limits under § 635.20(e), but could not retain them commercially. This will limit the ability of a small number of vessels to generate commercial revenue from sharks while landing shortfin mako sharks under the recreational size limits. In fact, there were only 35 General Category and 14 Charter/Headboat vessels with Directed or Incidental Shark permits in 2017. Between 2012 and 2017, shortfin mako sharks caught on hook and line or

handline only composed less than 1 percent of commercial landings. On an individual vessel basis, a prohibition on the landing of shortfin mako sharks is unlikely to affect the profitability of a commercial charter/headboat trip or the value of a shark incidental limited access permit on the open market. Ex-vessel prices for shortfin mako sharks are only around \$1.50 per pound while prices for yellowfin, bigeye, and bluefin tuna can range from \$3.50 to \$8.00 per pound (2017 SAFE Report). Thus, shortfin mako sharks are less valuable than target tuna species. Furthermore, other incidentally-caught sharks could still be legally retained and sold.

Similarly, a vessel issued both a Federal Atlantic commercial shark vessel permit under § 635.4(e) and an Atlantic Tunas General category permit under § 635.4(d) or a Swordfish General Commercial permit under § 635.4(f) with a shark endorsement could land shortfin mako sharks in accordance with the recreational size limits under § 635.20(e) when fishing in a registered HMS tournament § 635.4(c)(2). If a shortfin mako shark is retained by such vessels, any other shark species being retained cannot exceed the recreational retention limits under § 635.22(c) and cannot be sold.

Alternative B1, the no action alternative, would not implement any management measures in the recreational shark fishery to decrease mortality of shortfin mako sharks. This would result in no additional economic impacts on small entities associated with this fishery in the short-term.

Under Alternative B2, the preferred alternative, the minimum size limit for the retention of shortfin mako sharks would be increased from 54 inches FL to 71 inches FL for male and 83 inches FL for female shortfin mako sharks.

Under the proposed rule and Draft Amendment 11, Alternative B2 was not a preferred alternative. Instead, NMFS had preferred Alternative B3 which implemented a single size limit of 83 inches FL for all shortfin mako sharks. NMFS has decided to change that for a number of reasons including public comment, greater than estimated landings reductions under the 83 inch FL size limit implemented under the emergency interim rule, evidence of reduced directed effort for shortfin mako sharks under the emergency interim rule, and because this alternative would not increase harvest of mature female sharks compared to the 83 inch size limit implemented by the emergency interim final rule.

NMFS received a number of public comments urging the agency to adopt this alternative as the preferred

alternative, and implement the size limits specified in one of the measures of the ICCAT recommendation. Commenters pointed out that the U.S. delegation had supported the recommendation, and that U.S. recreational landings consisted of less than 5 percent of total international landings of shortfin mako sharks. As such, the added reduction in landings by implementing the 83 inch FL minimum size limit for both sexes would result in a minimal reduction of total international landings while greatly impacting the U.S. recreational fishery. Furthermore, any increases in shortfin mako landings under Alternative B2 would consist solely of male sharks as the minimum size limit for female sharks would remain the same.

This increase in the minimum size limit is projected to reduce recreational landings by at least 65 percent in numbers of sharks landed, and 50 percent in the weight of sharks landed. While this alternative would not establish a shortfin mako fishing season, such a significant increase in the minimum size limit would likely result in some reduction in directed fishing effort for shortfin mako sharks. Effort data collected via the LPS suggests there has been a significant reduction in directed fishing trips targeting shortfin mako sharks compared to the five year average under the 83 inch size limit implemented by the emergency interim final rule. Estimates of directed trips for shortfin mako sharks declined by 34 percent compared to the six year average from 2012 through 2017 resulting in greater than projected reductions in shortfin mako shark landings. This time period (June through August) traditionally accounts for over 90 percent of directed trips for shortfin mako sharks. Based on the LPS data from 2012–2017, shortfin mako sharks were the primary target species in approximately 67 percent of trips that caught and 75 percent of trips that landed them. As such, a reduction in directed fishing effort could substantially reduce the landings expected under this alternative. While this alternative is unlikely to affect directed effort as significantly as the 83 inch size limit, NMFS anticipates directed effort will not fully recover to previous levels.

Under Alternative B3, the minimum size limit for retention of shortfin mako sharks would be increased to 83 inches FL for both males and female sharks consistent with the measure implemented in the emergency rule. Assuming no reduction in directed fishing effort, this increase in the

minimum size limit would result in an 83 percent reduction in the number of sharks landed, and a 69 percent reduction in the weight of sharks landed. Such a large increase in the minimum size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort, in fact, an approximately 34 percent reduction in directed effort was observed in the summer of 2018 following the implementation of this size limit under the emergency interim final rule. An 83 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them by about 6 percent. At least three tournaments directed at shortfin mako sharks in the Northeast chose to cancel 2018 events due to the more stringent current 83 inches FL minimum size limit. Tournaments account for over half of directed recreational trips for shortfin mako sharks, and 77 percent of them in the month of June when effort is at its highest. This could result in a substantial reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators. NMFS no longer prefers Alternative B3 at this time as reduction in directed fishing effort following implementation of the emergency interim final rule suggests this alternative may be more restrictive than needed to achieve the reductions targets recommended by ICCAT, and could place an undue burden on the recreational fishery.

Under Alternative B4, recreational HMS permit holders would only be allowed to retain male shortfin mako sharks that measure at least 71 inches FL and female shortfin mako sharks that measure at least 108 inches FL. Assuming no reduction in directed fishing effort, this increase in the minimum size limit would result in a 77 percent reduction in the number of sharks landed. A 73 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to approximately 9 percent. This could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B5, recreational HMS permit holders would only be allowed to retain male shortfin mako sharks that measure at least 71 inches FL and female shortfin mako sharks that measure at least 120 inches FL. Assuming no reduction in directed fishing effort, this increase in the size

limit would result in a 78 percent reduction in the number of sharks landed, and a 74 percent reduction in the weight of sharks landed. A 78 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8.6 percent. This could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6a, the minimum size limit for the retention of shortfin mako sharks would be increased from 54 inches FL to 71 inches FL for male and 83 inches FL for female shortfin mako sharks, and a shortfin mako fishing season would be established from May through October. The fishing season established under this alternative would have little to no effect on shortfin mako fishing activity in the Northeast, but may reduce fishing effort in the South Atlantic and Gulf of Mexico regions; however, a lack of data on targeted trips for shortfin mako sharks in this region makes any assessment of potential socioeconomic impacts difficult. However, this combination of increase in the size limit and fishing season is projected to reduce recreational landings by at least 65 percent in numbers of sharks landed, and 50 percent in the weight of sharks landed in the Northeast. A 65 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 13 percent. This reduction on directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators. NMFS does not prefer this alternative at this time, as it is unlikely to result in significantly greater reductions in landings than the preferred alternative, Alternative B2, and could potentially result in regional inequalities in access to the recreational shortfin mako shark fishery due to difference in seasonal abundance.

Under Alternative B6b, NMFS would establish a three-month fishing season for shortfin mako sharks spanning the summer months of June through August. This season would be combined with a 71-inch FL minimum size limit for males and 100 inch minimum size FL for females. Based on estimates from the LPS, on average 475 directed trips are taken for shortfin mako sharks each September and October, representing approximately 9 percent of all annual directed trips. No registered HMS tournaments held in September and October target sharks exclusively, so it is highly unlikely this alternative would

result in the rescheduling of any tournaments due to the fishing season. It is much more likely that directed fishing effort would be affected by the increases in the minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in a 79 percent reduction in the number of sharks landed, and a 74 percent reduction in the weight of sharks landed. This reduction could result in a significant reduction in directed fishing trips for shortfin mako sharks, thus leading to moderate adverse economic impacts on some charter/headboat operators. NMFS does not prefer this alternative at this time as observed reductions in directed fishing effort following implementation of the emergency interim rule suggest this alternative may be more restrictive than is needed to meet the 72 to 79 percent reduction targets recommended by ICCAT.

Under Alternative B6c, NMFS would establish a two-month fishing season for shortfin mako sharks for the months of June and July. This season would be combined with a 71-inch FL minimum size limit for males and 90-inch minimum sizes FL for females. Based on estimates from the LPS, on average 1,264 directed trips are taken for shortfin mako sharks each August through October, representing approximately 26 percent of all annual directed trips. Only two registered HMS tournaments held in August through October target sharks exclusively, one out of New York that primarily targets thresher sharks and one out of Florida where participants fish exclusively from shore. Thus, it is highly unlikely this alternative would result in the rescheduling of any tournaments due to the fishing season. It is likely that directed fishing effort would also be affected by the increases in the minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in a 77 percent reduction in the number of sharks landed, and a 69 percent reduction in the weight of sharks landed. Such a large increase in the size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort. A 77 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8 percent. This reduction in

directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators. NMFS does not prefer this alternative at this time as observed reductions in directed fishing effort following implementation of the emergency interim rule suggest this alternative may be more restrictive than is needed to meet the 72 to 79 percent reduction targets recommended by ICCAT.

Under Alternative B6d, NMFS would establish a one-month fishing season for shortfin mako sharks for the month of June only. This season would be combined with a 71 inches FL minimum size limit for males and 83 inches FL for females. Based on estimates from the LPS, on average 2,435 directed trips are taken for shortfin mako sharks each July through October, representing approximately 52 percent of all annual directed trips. Additionally, there are seven registered HMS tournaments held in July through October that target sharks exclusively, including three of four tournaments held in the state of Rhode Island, and the only tournament in Massachusetts to target sharks exclusively. It is likely that directed fishing effort would also be affected by the increases in the minimum size limits. Assuming this increase in the size limit has minimal effect on fishing effort directly towards shortfin mako sharks within the season, this combination of season and increase in the size limit should result in an 80 percent reduction in the number of sharks landed, and a 76 percent reduction in the weight of sharks landed. Such a large increase in the size limit and associated reduction in landings is unlikely to have no effect on directed fishing effort. An 80 percent reduction in shortfin mako sharks harvested would thus reduce the percentage of directed trips harvesting them to 8 percent. This reduction in directed trips could lead to moderate adverse economic impacts on some charter/headboats and tournament operators.

Under Alternative B6e, NMFS would establish a process and criteria for determining season dates and minimum size limits for shortfin mako sharks on an annual basis through inseason actions. This process would be similar to how the agency sets season opens and retention limits for the shark commercial fisheries and the Atlantic Tunas General category fishery. NMFS would review data on recreational landings, catch rates, and effort levels for shortfin mako sharks in the previous years, and establish season dates and minimum size limits that would be

expected to achieve the reduction targets established by ICCAT, and the objectives of the HMS fisheries management plan. This alternative would also allow NMFS to minimize adverse economic impacts to the HMS recreational fishery by allowing for adjustments to the season and size limits based on observed reductions and redistribution of fishing effort resulting from measures implemented in previous years. NMFS does not prefer this alternative at this time as the establishment of a shortfin mako shark fishing season has the potential to create regional inequalities in access to the fishery given its wide spatial and temporal nature as a highly migratory species. These potential inequalities would appear to be unjustified as there are alternatives available that are capable of meeting the reductions recommended by ICCAT without them.

Under Alternative B7, NMFS would implement a "slot limit" for shortfin mako sharks in the recreational fishery. Under a slot limit, recreational fishermen would only be allowed to retain shortfin mako sharks within a narrow size range (*e.g.*, between 71 and 83 inches FL) with no retention above or below that slot. Assuming no reduction in directed fishing effort, this alternative would be expected to result in similar reductions in landings as other alternatives analyzed here. While this alternative would not establish a shortfin mako fishing season, as described above in earlier alternatives, such a significant increase in the size limit would likely result in some reduction in directed fishing effort for shortfin mako sharks and shifting focus to other HMS species. This reduction in effort may be further exacerbated by the complicated nature of slot limits regulations. The amount of effort reduction by recreational fishermen would depend on how much HMS anglers and tournaments are satisfied to practice catch-and-release fishing for sub-legal shortfin mako sharks or shift their fishing effort to other species. NMFS does not prefer this alternative at this time as there are less complicated options available that are capable of meeting the mortality reductions recommended by ICCAT.

Under Alternative B8, NMFS would establish a landings tag requirement and a yearly limit on the number of landings tags assigned to a vessel, for shortfin mako sharks over the minimum size limit. This requirement would be expected to negatively affect fishing effort. An increase in the minimum size limit and a yearly cap on landings for vessels would reduce effort drastically, while maintaining some opportunity for

the recreational fleet. This effort reduction would adversely affect the charter fleet the most by limiting the number of trips on which they could land shortfin mako sharks each year. This effort reduction may also affect their ability to book trips. At least one tournament directed at shortfin mako sharks in the Northeast chose to cancel its 2018 event due to the more stringent current 83-inch FL minimum size limit. By excluding tournaments from a landings tag requirement there may be a direct beneficial economic impact for tournaments, as this would be an additional opportunity, beyond their tags, to land shortfin mako sharks for permit holders.

Alternative B9, the preferred alternative, would expand the requirement to use non-offset, non-stainless steel circle hook by all HMS permit holders with a shark endorsement when fishing for sharks recreationally, except when fishing with flies or artificial lures, in federal waters. Currently, this requirement is in place for all federally managed waters south of 41°43' N latitude (near Chatham, Massachusetts), but this alternative would remove the boundary line, requiring fishermen in all areas to use circle hooks. Recreational shark fishermen north of Chatham, Massachusetts would need to purchase circle hooks to comply with this requirement, although the cost is modest. Additionally, it is possible that once the circle hook requirement is expanded, fishermen in the newly impacted area could find reduced catch rates of sharks including shortfin mako sharks. If reduced catch rates are realized, effort in the recreational shark fishery, including the for-hire fleet, could be impacted by reduced number of trips or reduced demand for chartered trips.

Alternative B10 would place shortfin mako sharks on the prohibited sharks list to prohibit the retention of shortfin mako sharks in recreational HMS fisheries. HMS permit holders would be prohibited from retaining or landing shortfin mako sharks recreationally. In recreational fisheries, recreational fishermen would only be authorized to catch and release shortfin mako sharks. A prohibition on the retention of shortfin mako sharks is likely to disincentivize some portion of the recreational shark fishery, particularly those individuals that plan to target shortfin mako sharks. Businesses that rely on recreational shark fishing such as and tournament operators and charter/headboats may experience a decline in demand resulting in adverse economic impacts. NMFS does not prefer this

alternative at this time as it would prohibit all retention of shortfin mako sharks in the recreational fishery. As such, Alternative B10 would create unnecessary inequalities between the commercial and recreational fishing sectors when other alternatives are available that can achieve the ICCAT recommended landings reduction in a more equitable fashion.

Alternative C1, the preferred alternative, would make no changes to the current reporting requirements applicable to shortfin mako sharks in HMS fisheries. Since there would be no changes to the reporting requirements under this alternative, NMFS would expect fishing practices to remain the same and direct economic impacts in small entities to be neutral in the short-term.

Under Alternative C2, NMFS would require vessels with a directed or incidental shark LAP to report daily the number of shortfin mako sharks retained and discarded dead, as well as fishing effort (number of sets and number of hooks) on a VMS. A requirement to report shortfin mako shark catches on VMS for vessels with a shark LAP would be an additional reporting requirement for those vessels on their existing systems. For other commercial vessels that are currently only required to report in the HMS logbook, the requirement would mean installing VMS to report dead discards of shortfin mako and fishing effort.

If a vessel has already installed a type-approved E-MTU VMS unit, the only expense would be monthly communication service fees, which it may already be paying if the vessel is participating in a Council-managed fishery. Existing regulations require all vessel operators with E-MTU VMS units to provide hail out/in declarations and provide location reports on an hourly basis at all times while they are away from port. In order to comply with these regulations, vessel owners must subscribe to a communication service plan that includes an allowance for sending similar declarations (hail out/in) describing target species, fishing gear possessed, and estimated time/location of landing using their E-MTU VMS. Given that most shortfin mako sharks are incidentally caught by pelagic longline vessels that are already required to have an E-MTU VMS system onboard, adverse economic impacts are not expected. If vessels with a shark LAP do not have an E-MTU VMS unit, direct, economic costs are expected as a result of having to pay for the E-MTU VMS unit (approximately \$4,000) and a qualified marine electrician to install the unit (\$400).

VMS reporting requirements under this alternative could potentially provide undue burden to HMS commercial vessels that already report on catches, landings, and discards through vessel logbooks, dealer reports, and observer reports.

Alternative C3 would implement mandatory reporting of all recreational interactions (landed and discarded) of shortfin mako sharks in HMS fisheries. Recreational HMS permit holders would have a variety of options for reporting shortfin mako shark landings including a phone-in system, internet website, and/or a smartphone app. HMS Angling and Charter/Headboat permit holders currently use this method for required reporting of each individual landing of bluefin tuna, billfish, and swordfish within 24 hours. NMFS has also maintained a shortfin mako shark reporting app as an educational tool to encourage the practice of catch-and-release. Additionally, the potential burden associated with mandatory landings reports for shortfin mako sharks would be significantly reduced under the increased minimum size limits being considered in this rulemaking, although would still represent an increased burden over current reporting requirements. While HMS Angling permit holders are not considered small entities by NMFS for purposes of the Regulatory Flexibility Act, Charter/Headboat permit holders are considered to be small entities and would be potentially impacted by this alternative.

Under Alternative D1, NMFS would not establish a rebuilding plan or the foundation for rebuilding the shortfin mako shark stock. NMFS would still implement management measures in the HMS recreational and commercial fisheries to end overfishing consistent with the Magnuson-Stevens Act and with ICCAT Recommendation 17–08 and our obligations under ATCA. There would likely be no direct short-term impact on small entities from this alternative as there would be no change in fishing effort or landings of shortfin mako sharks that would impact revenues generated from the commercial and recreational fisheries.

Under Alternative D2, NMFS would establish a domestic rebuilding plan independent of a rebuilding plan adopted by ICCAT. While such an alternative could avoid overfishing shortfin mako sharks in the United States by changing the way that the U.S. recreational and commercial fisheries operate, such a plan could not effectively rebuild the stock, since U.S. catches are only 9 percent of the reported catch Atlantic-wide. Such an

alternative would be expected to cause short- and long-term direct economic impacts.

Under Alternative D3, the preferred alternative, NMFS would take preliminary action toward rebuilding by adopting measures to end overfishing to establish the foundation for a rebuilding plan. NMFS would then take action at the international level through ICCAT to develop a rebuilding plan for shortfin mako sharks. ICCAT may establish a rebuilding plan for shortfin mako sharks in 2019, and this rebuilding plan would encompass the objectives set forth by ICCAT based on scientific advice from the SCRS. This alternative would not result in any changes to the current recreational and commercial domestic regulations for shortfin mako sharks in the short-term. There would likely be no direct short-term impact on small entities from this alternative as there would be no change in fishing effort or landings of shortfin mako sharks that would impact revenues generated from the commercial and recreational fisheries. Management measures to address overfishing of shortfin mako sharks could be adopted in the future. These measures could change the way that the U.S. recreational and commercial shortfin mako shark fishery operates, which could cause long-term direct economic impacts. Any future action to implement international measures would be analyzed in a separate rulemaking.

Under Alternative D4, NMFS would remove shortfin mako sharks from the commercial pelagic shark management group and would implement a species-specific quota for shortfin mako sharks as established by ICCAT. A shortfin mako-specific quota would likely include both commercial and recreational catches, as do other ICCAT established quotas. In addition, NMFS would establish a new commercial pelagic shark species quota for common thresher and oceanic whitetip sharks based on recent landings. The 2017 ICCAT stock assessment indicated that the North Atlantic population of shortfin mako sharks is overfished and experiencing overfishing. In November 2017, ICCAT adopted management measures (Recommendation 17–08) to address the overfishing determination, but did not recommend a TAC necessary to stop overfishing of shortfin mako sharks. Therefore, it is difficult at this time to determine how setting a species-specific quota for shortfin mako sharks would affect commercial and recreational fishing operations. However, this species-specific quota may provide long-term direct, minor adverse economic impacts if ICCAT

established a TAC for the United States that is well below the total average harvest by the United States (*i.e.*, 330 mt ww or 168 mt dw) or below the current annual commercial quota for common thresher, oceanic whitetip, and shortfin mako (488 mt dw) as it could potentially limit the amount of harvest for fishermen. Short-term direct socioeconomic impacts would be neutral for Alternative D4 because initially there would be no reduction in fishing effort and practices.

Under Alternative D5, NMFS would take steps to implement area-based management measures domestically if such measures are established by ICCAT. ICCAT Recommendation 17–08 calls on the SCRS to provide additional scientific advice in 2019 that takes into account a spatial/temporal analysis of North Atlantic shortfin mako shark catches in order to identify areas with high interactions. Without a specific area to analyze at this time, the precise impacts on commercial and recreational fishery operations cannot be determined. Implementing area management for shortfin mako sharks, if recommended by the scientific advice, could lead to a reduction in localized fishing effort, which would likely have adverse economic impacts for small entities that land shortfin mako sharks.

Under Alternative D6, NMFS would annually allocate a specific number of “allowable” dead discards of shortfin mako sharks as a bycatch cap or sub-annual catch limit (ACL) that would apply to all fisheries, not just HMS fisheries. This alternative would impact the HMS pelagic longline and shark recreational fisheries similar to Alternative D4. However, this alternative could also impact non-HMS fisheries by closing those fisheries if the bycatch cap were reached. This alternative could lead to short-term adverse impacts since the bycatch caps could close fisheries if they are reached until those fishermen could modify fishing behavior to avoid shortfin mako sharks (even in fisheries where shortfin mako sharks are rarely, if ever, seen) and reduce interactions. In the long-term, this alternative would have neutral impacts as the vessels would avoid shortfin mako sharks. The impacts to small businesses are expected to be neutral in the short and long-term as their businesses would not change.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such

publications as “small entity compliance guides.” The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, NMFS has prepared a listserv summarizing fishery information and regulations for Atlantic shark fisheries for 2019. This listserv also serves as the small entity compliance guide. Copies of the compliance guide are available from NMFS (see ADDRESSES).

NMFS prepared a FEIS for this final rule that discusses the impact on the environment that would result from this rule. A copy of the FEIS is available from NMFS (see ADDRESSES).

List of Subjects in 50 CFR Part 635

Fisheries, Fishing, Fishing vessels, Foreign relations, Imports, Penalties, Reporting and recordkeeping requirements, Treaties.

Dated: February 15, 2019.

Samuel D. Rauch III,

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

For the reasons set out in the preamble, 50 CFR part 635 is amended as follows:

PART 635—ATLANTIC HIGHLY MIGRATORY SPECIES

1. The authority citation for part 635 continues to read as follows:

Authority: 16 U.S.C. 971 et seq.; 16 U.S.C. 1801 et seq.

2. In § 635.2, revise definition of “FL (fork length)” to read as follows:

§ 635.2 Definitions.

* * * * *

FL (fork length) means the straight-line measurement of a fish from the midpoint of the anterior edge of the fish to the fork of the caudal fin. The measurement is not made along the curve of the body.

* * * * *

3. In § 635.20, lift the suspension on paragraph (e)(2) and revising it and by adding paragraph (e)(6) to read as follows:

§ 635.20 Size limits.

* * * * *

(e) * * *

(2) All sharks, except as otherwise specified in paragraphs (e)(3) through (6) of this section, landed under the recreational retention limits specified at § 635.22(c)(2) must be at least 54 inches (137 cm) FL.

* * * * *

(6) For North Atlantic shortfin mako sharks landed under the recreational retention limits specified at § 635.22(c)(2), males must be at least 71 inches (180 cm) fork length, and females must be at least 83 inches (210 cm) fork length.

* * * * *

- 4. Amend § 635.21 by:
a. Adding paragraphs (a)(4), (c)(1)(iv), and (d)(5);
b. Revising paragraphs (f)(2) and (3);
c. Adding paragraph (g)(6); and
d. Revising (k)(1) and (2).

The additions and revisions read as follows:

§ 635.21 Gear operation and deployment restrictions.

(a) * * *

(4) Any person on board a vessel that is issued a commercial shark permit must release all shortfin mako sharks, whether alive or dead, caught with any gear other than pelagic longline, bottom longline, or gillnet gear, except that any person on board a vessel that is issued a commercial shark permit in combination with a permit that has a shark endorsement may retain shortfin mako sharks subject to the recreational minimum size limits in § 635.20, the recreational retention limits in § 635.22, and authorized gear requirements in § 635.19.

* * * * *

(c) * * *

(1) * * *

(iv) Has pelagic longline gear on board, persons aboard that vessel are required to promptly release in a manner that causes the least harm any shortfin mako shark that is alive at the time of haulback. Any shortfin mako shark that is dead at the time of haulback may be retained provided the electronic monitoring system is installed and functioning in compliance with the requirements at § 635.9.

* * * * *

(d) * * *

(5) If a vessel issued or required to be issued a permit under this part has bottom longline gear on board persons aboard that vessel are required to promptly release in a manner that causes the least harm, any shortfin mako shark that is alive at the time of haulback.

* * * * *

(f) * * *

(2) A person on board a vessel that has been issued or is required to be issued a permit with a shark endorsement under this part and who is participating in an HMS registered tournament that bestows points, prizes, or awards for Atlantic sharks must

deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

(3) A person on board a vessel that has been issued or is required to be issued an HMS Angling permit with a shark endorsement or an HMS Charter/Headboat permit with a shark endorsement must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

* * * * *

(g) * * *

(6) If a vessel issued or required to be issued a permit under this part has gillnet gear onboard, persons aboard that vessel are required to promptly release in a manner that causes the least harm any shortfin mako shark that is alive at the time of haulback.

* * * * *

(k) * * *

(1) A person on board a vessel that has been issued or is required to be issued a permit with a shark endorsement under this part and who is participating in an HMS registered tournament that bestows points, prizes, or awards for Atlantic sharks must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing sharks, except when fishing with flies or artificial lures.

(2) A person on board a vessel that has been issued or is required to be issued an HMS Angling permit with a shark endorsement or a person on board a vessel with an HMS Charter/Headboat permit with a shark endorsement must deploy only non-offset, corrodible circle hooks when fishing for, retaining, possessing, or landing, except when fishing with flies or artificial lures.

* * * * *

5. In § 635.22, revise paragraph (c)(1) and add paragraph (c)(7) as follows:

§ 635.22 Recreational Retention Limits.

(c) * * *

(1) The recreational retention limit for sharks applies to any person who fishes in any manner on a vessel that has been issued or is required to have been issued a permit with a shark endorsement, except as noted in paragraph (c)(7) of this section. The retention limit can change depending on the species being caught and the size limit under which they are being caught as specified under § 635.20(e). A person on board a vessel that has been issued or is required to be issued a permit with a shark endorsement under § 635.4 is required

to use non-offset, corrodible circle hooks as specified in § 635.21(f) and (k) in order to retain sharks per the retention limits specified in this section.

* * * * *

(7) For persons on board vessels issued both a commercial shark permit and a permit with a shark endorsement, the recreational retention limit and sale prohibition applies for shortfin mako sharks at all times, even when the commercial pelagic shark quota is open. If such vessels retain a shortfin mako shark under the recreational retention limit, all other sharks retained by such vessels may only be retained under the applicable recreational retention limits and may not be sold. If a commercial Atlantic shark quota is closed under § 635.28(b), the recreational retention limit for sharks and no sale provision in paragraph (a) of this section will be applied to persons aboard a vessel issued a Federal Atlantic commercial shark vessel permit under § 635.4(e), if that vessel has also been issued a permit with a shark endorsement under § 635.4(b) and is engaged in a for-hire fishing trip or is participating in a registered HMS tournament per § 635.4(c)(2).

* * * * *

■ 6. In § 635.24, lift the suspension on paragraphs (a)(4)(i) and (iii), and revise them to read as follows:

§ 635.24 Commercial retention limits for sharks, swordfish, and BAYS tunas.

* * * * *

- (a) * * *
- (4) * * *

(i) Except as provided in § 635.22(c)(7), a person who owns or operates a vessel that has been issued a directed shark LAP may retain, possess, land, or sell pelagic sharks if the pelagic shark fishery is open per §§ 635.27 and 635.28. Shortfin mako sharks may be retained by persons aboard vessels using pelagic longline, bottom longline, or gillnet gear only if the shark is dead at the time of haulback and consistent with the provisions of § 635.21(c)(1), (d)(5), and (g)(6) and 635.22(c)(7).

* * * * *

(iii) Consistent with paragraph (a)(4)(ii) of this section, a person who owns or operates a vessel that has been issued an incidental shark LAP may retain, possess, land, or sell no more than 16 SCS and pelagic sharks, combined, per vessel per trip, if the respective fishery is open per §§ 635.27 and 635.28. Of those 16 SCS and pelagic sharks per vessel per trip, no more than 8 shall be blacknose sharks. Shortfin mako sharks may only be retained under the commercial retention limits by

persons using pelagic longline, bottom longline, or gillnet gear, only if the shark is dead at the time of haulback and consistent with the provisions at § 635.21(c)(1), (d)(5), and (g)(6). If the vessel has also been issued a permit with a shark endorsement and retains a shortfin mako shark, recreational retention limits apply to all sharks retained and none may be sold, per § 635.22(c)(7).

* * * * *

■ 7. In § 635.30, paragraph (c)(4) is revised to read as follows:

* * * * *

(c) * * *

(4) Persons aboard a vessel that has been issued or is required to be issued a permit with a shark endorsement must maintain a shark intact through landing and offloading with the head, tail, and all fins naturally attached. The shark may be bled and the viscera may be removed.

* * * * *

■ 8. In § 635.71, revise paragraphs (d)(22), (23), (27), (28), and (29) to read as follows:

§ 635.71 Prohibitions.

* * * * *

(d) * * *

(22) Except when fishing only with flies or artificial lures, fish for, retain, possess, or land sharks without deploying non-offset, corrodible circle hooks when fishing at a registered recreational HMS fishing tournament that has awards or prizes for sharks, as specified in § 635.21(f) and (k).

(23) Except when fishing only with flies or artificial lures, fish for, retain, possess, or land sharks without deploying non-offset, corrodible circle hooks when issued an Atlantic HMS Angling permit or HMS Charter/Headboat permit with a shark endorsement, as specified in § 635.21(f) and (k).

* * * * *

(27) Retain, land, or possess a shortfin mako shark that was caught with gear other than pelagic longline, bottom longline, or gillnet gear as specified at § 635.21(a).

(28) Retain, land, or possess a shortfin mako shark that was caught with pelagic longline, bottom longline, or gillnet gear and was alive at haulback as specified at § 635.21(c)(1), (d)(5), and (g)(6).

(29) As specified at § 635.21(c)(1), retain, land, or possess a shortfin mako shark that was caught with pelagic longline gear when the electronic monitoring system was not installed and

functioning in compliance with the requirements at § 635.9.

* * * * *

[FR Doc. 2019-02946 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170828822-70999-04]

RIN 0648-XG796

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of North Carolina is transferring a portion of its 2019 commercial summer flounder quota to the State of New Jersey. This quota adjustment is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan quota transfer provisions. This announcement informs the public of the revised commercial quotas for North Carolina and New Jersey.

DATES: Effective February 20, 2019, through December 31, 2019.

FOR FURTHER INFORMATION CONTACT: Cynthia Ferrio, Fishery Management Specialist, (978) 281-9180.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.110. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the initial 2019 allocations were published on December 17, 2018 (83 FR 64482).

The final rule implementing Amendment 5 to the Summer Flounder Fishery Management Plan, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder

commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider the criteria in § 648.102(c)(2)(i)(A) through (C) in the evaluation of requests for quota transfers or combinations.

North Carolina is transferring 3,270 lb (1,483 kg) of summer flounder commercial quota to New Jersey through mutual agreement of the states. This transfer was requested to repay landings made by a North Carolina-permitted vessel in New Jersey under a safe harbor agreement. Based on the initial quotas published in the 2019 Summer Flounder, Scup, and Black Sea Bass Specifications, the revised summer flounder quotas for fishing year 2019 are now: North Carolina, 1,827,368 lb (828,880 kg); and New Jersey, 1,118,827 lb (507,491 kg).

Classification

This action is taken under 50 CFR part 648 and is exempt from review under Executive Order 12866.

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

Dated: February 15, 2019.

Karen H. Abrams,

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

[FR Doc. 2019-02922 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648-XG797

Pacific Island Fisheries; 2019 Northwestern Hawaiian Islands Lobster Harvest Guideline

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

ACTION: Notification of lobster harvest guideline.

SUMMARY: NMFS establishes the annual harvest guideline for the commercial lobster fishery in the Northwestern Hawaiian Islands (NWHI) for calendar year 2019 at zero lobsters.

DATES: February 21, 2019.

FOR FURTHER INFORMATION CONTACT: Bob Harman, NMFS PIR Sustainable Fisheries, tel 808-725-5170.

SUPPLEMENTARY INFORMATION: NMFS manages the NWHI commercial lobster fishery under the Fishery Ecosystem Plan for the Hawaiian Archipelago. The regulations at 50 CFR 665.252(b) require NMFS to publish an annual harvest guideline for lobster Permit Area 1, comprised of Federal waters around the NWHI.

Regulations governing the Papahānaumokuākea Marine National Monument in the NWHI prohibit the unpermitted removal of monument resources (50 CFR 404.7), and establish a zero annual harvest guideline for lobsters (50 CFR 404.10(a)). Accordingly, NMFS establishes the harvest guideline for the NWHI commercial lobster fishery for calendar year 2018 at zero lobsters. Harvest of NWHI lobster resources is not allowed.

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

Dated: February 15, 2019.

Karen H. Abrams,

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

[FR Doc. 2019-02986 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

Proposed Rules

Federal Register

Vol. 84, No. 35

Thursday, February 21, 2019

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Document Number AMS–SC–18–0023]

Mango Promotion, Research and Information Order; Referendum on Inclusion of Frozen Mangos

AGENCY: Agricultural Marketing Service.

ACTION: Notification of referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible first handlers and importers of mangos to determine whether they favor the inclusion of frozen mangos as a covered commodity under the Mango Promotion, Research and Information Order (Order).

DATES: This referendum will be conducted from March 25, 2019 through April 12, 2019. The U.S. Department of Agriculture (Department) will provide the option for electronic ballots. Further details will be provided in the ballot instructions. First handlers who received 500,000 or more pounds of fresh mangos from producers and importers who imported 500,000 or more pounds of fresh mangos or 200,000 or more pounds of frozen mangos into the United States, during the representative period from January 1 through December 31, 2017, are eligible to vote. Mail ballots must be postmarked by April 12, 2019. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. Eastern Time (ET) on April 12, 2019.

ADDRESSES: Copies of the Order may be obtained from: Referendum Agent, Promotion and Economics Division (PED), Specialty Crops Program (SCP), AMS, USDA, Stop 0244, Room 1406–S, 1400 Independence Avenue SW, Washington, DC 20250–0244; telephone: (202) 720–9915, (202) 720–5976 (direct line); facsimile: (202) 205–2800.

FOR FURTHER INFORMATION CONTACT: Jeanette Palmer, Marketing Specialist,

PED, SCP, AMS, USDA, Stop 0244, Room 1406–S, 1400 Independence Avenue SW, Washington, DC 20250–0244; telephone: (202) 720–9915, (202) 720–5976 (direct line); facsimile: (202) 205–2800; or electronic mail: Jeanette.Palmer@ams.usda.gov.

SUPPLEMENTARY INFORMATION: Pursuant to the Commodity Promotion, Research and Information Act of 1996 (7 U.S.C. 7411–7425) (1996 Act), it is hereby directed that a referendum be conducted to ascertain whether the inclusion of frozen mangos in the Order is favored by eligible first handlers of fresh mangos and importers of fresh and frozen mangos covered under the program. Recently, the Order was modified to add frozen mangos as a covered commodity, and importers of frozen mangos will be assessed one cent (\$0.01) per pound on frozen mangos. In addition, the National Mango Board membership has been expanded from 18 to 21 with the addition of two seats for importers of frozen mangos and one seat for a foreign processor. As these changes to the Order involve new covered entities, the Department determines that it is appropriate to conduct a referendum on the provisions regarding frozen mangos to ensure that those covered under the program agree with continuation of the Order as modified.

The representative period for establishing voter eligibility for the referendum shall be the period from January 1 through December 31, 2017. First handlers who received 500,000 or more pounds of fresh mangos from producers and importers who imported 500,000 or more pounds of fresh mangos or 200,000 or more pounds of frozen mangos into the United States during the representative period are eligible to vote. Persons who received an exemption from assessments for the entire representative period are ineligible to vote. The referendum shall be conducted by mail ballot from March 25, through April 12, 2019. The Department will provide the option for electronic ballots. Further details will be provided in the ballot instructions.

Section 518(d) of the Act authorizes referenda at any time to determine whether the continuation, suspension, or termination of the order or a provision of the order is favored by persons eligible to vote. The Department would retain the provisions of the Order that added frozen mangos to the

program if approved by a majority of the first handlers and importers voting in the referendum. If not approved, the Department will conduct rulemaking to remove the provisions from the Order.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the referendum ballot has been approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0093. It has been estimated that there are approximately five first handlers and 275 importers of fresh mangos and 190 importers of frozen mangos who will be eligible to vote in the referendum. It will take an average of 15 minutes for each voter to read the voting instructions and complete the referendum ballot.

Referendum Order

Jeanette Palmer, Marketing Specialist and Heather Pichelman, Director, Promotion and Economics Division, SCP, AMS, USDA, Stop 0244, Room 1406–S, 1400 Independence Avenue SW, Washington, DC 20250–0244, are designated as the referendum agents to conduct this referendum. The referendum procedures at 7 CFR 1206.100 through 1206.108, which were issued pursuant to the Act, shall be used to conduct the referendum.

The referendum agents will distribute the ballots to be cast in the referendum and voting instructions to all known first handlers who received 500,000 or more pounds of fresh mangos from producers and importers who imported 500,000 or more pounds of fresh mangos or 200,000 or more of frozen mangos into the United States during the representative period, prior to the first day of the voting period. Persons who are eligible first handlers or importers during the representative period and are first handlers or importers at the time of the referendum are eligible to vote. Persons who received an exemption from assessments during the entire representative period are ineligible to vote. Any eligible first handler or importer who does not receive a ballot should contact a referendum agent no later than one week before the end of the voting period. Mail ballots must be postmarked by April 12, 2019. Ballots delivered via express mail or email must show proof of delivery by no later than 11:59 p.m. Eastern Time (ET) on April 12, 2019.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Marketing agreements, Mango promotion, Reporting and recordkeeping requirements.

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

Dated: February 14, 2019.

Bruce Summers,

Administrator.

[FR Doc. 2019–02851 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL DEPOSIT INSURANCE CORPORATION**12 CFR Part 327**

RIN 3064–AE98

Assessments

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) invites public comment on a notice of proposed rulemaking (NPR or proposal) that would amend its deposit insurance assessment regulations to apply the community bank leverage ratio (CBLR) framework to the deposit insurance assessment system. The FDIC, the Board of Governors of the Federal Reserve System (Federal Reserve) and the Office of the Comptroller of the Currency (OCC) (collectively, the Federal banking agencies) recently issued an interagency proposal to implement the community bank leverage ratio (the CBLR NPR). Under this proposal, the FDIC would assess all banks that elect to use the CBLR framework (CBLR banks) as small banks. Through amendments to the assessment regulations and corresponding changes to the Consolidated Reports of Condition and Income (Call Report), CBLR banks would have the option of using either CBLR tangible equity or tier 1 capital for their assessment base calculation, and using either the CBLR or the tier 1 leverage ratio for the Leverage Ratio that the FDIC uses to calculate an established small bank's assessment rate. Through this NPR, the FDIC also would clarify that a CBLR bank that meets the definition of a custodial bank would have no change to its custodial bank deduction or reporting items required to calculate the deduction; and the assessment regulations would continue to reference the prompt corrective action (PCA) regulations for

the definitions of capital categories used in the deposit insurance assessment system, with technical amendments to align with the CBLR NPR. To assist banks in understanding the effects of the NPR, the FDIC plans to provide on its website an assessment estimation tool that estimates deposit insurance assessment amounts under the proposal.

DATES: Comments must be received on or before April 22, 2019.

ADDRESSES: You may submit comments, identified by RIN 3064–AE98, by any of the following methods:

- *Agency website:* <https://www.fdic.gov/regulations/laws/federal/>. Follow the instructions for submitting comments on the Agency website.

- *Email:* Comments@FDIC.gov.

Include RIN 3064–AE98 in the subject line of the message.

- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429. Include RIN 3064–AE98 in the subject line of the letter.

- *Hand Delivery/Courier:* Guard station at the rear of the 550 17th Street NW building (located on F Street) on business days between 7 a.m. and 5 p.m. (EDT).

- *Public Inspection:* All comments received, including any personal information provided, will be posted without change to <https://www.fdic.gov/regulations/laws/federal/>. Paper copies of public comments may be ordered from the FDIC Public Information Center, 3501 North Fairfax Drive, Room E–1002, Arlington, VA 22226 or by telephone at (877) 275–3342 or (703) 562–2200.

FOR FURTHER INFORMATION CONTACT: Ashley Mihalik, Chief, Banking and Regulatory Policy Section, Division of Insurance and Research, (202) 898–3793, amihalik@fdic.gov; Daniel Hoople, Financial Economist, Banking and Regulatory Policy Section, Division of Insurance and Research, dhoople@fdic.gov; (202) 898–3835; Nefretete Smith, Counsel, Legal Division, (202) 898–6851, NefSmith@fdic.gov.

SUPPLEMENTARY INFORMATION:**I. Policy Objectives**

The Federal Deposit Insurance Act (FDI Act) requires that the FDIC establish a risk-based deposit insurance assessment system.¹ Pursuant to this

¹ 12 U.S.C. 1817(b). Generally, a “risk-based assessment system” means a system for calculating a depository institution’s assessment based on the institution’s probability of causing a loss to the Deposit Insurance Fund (DIF) due to the composition and concentration of the institution’s assets and liabilities, the likely amount of any such

requirement, the FDIC first adopted a risk-based deposit insurance assessment system effective in 1993 that applied to all insured depository institutions (IDIs).² The FDIC implemented a risk-based assessment system with the goals of making the deposit insurance system fairer to well-run institutions and encouraging weaker institutions to improve their condition, and thus, promote the safety and soundness of IDIs.³ Deposit insurance assessments based on risk also provide incentives for IDIs to monitor and reduce risks that could increase potential losses to the DIF. Since 1993, the FDIC has met its statutory mandate and has pursued these policy goals by periodically introducing improvements to the deposit insurance assessment system’s ability to differentiate for risk.

The primary objective of this proposal is to incorporate the CBLR framework⁴ into the current risk-based deposit insurance assessment system in a manner that: (1) Maximizes regulatory relief for small institutions that use the CBLR framework; and (2) minimizes increases in deposit insurance assessments that may arise without a change in risk. The rulemaking also would maintain fair and appropriate pricing of deposit insurance for institutions that use the CBLR.

II. Background

The FDIC assesses all IDIs an amount for deposit insurance equal to the bank’s⁵ deposit insurance assessment base multiplied by its risk-based assessment rate.⁶ A bank’s assessment base and risk-based assessment rate depend in part, on tier 1 capital and the tier 1 leverage ratio. This information would no longer be reported on the Consolidated Reports of Condition and Income (Call Report) by banks that elect the CBLR framework.

A. Notice of Proposed Rulemaking: Community Bank Leverage Ratio

On February 8, 2019, the Federal banking agencies published in the **Federal Register** the CBLR NPR.⁷ The CBLR NPR would provide for a

loss, and the revenue needs of the DIF. See 12 U.S.C. 1817(b)(1)(C).

² 57 FR 45263 (Oct. 1, 1992).

³ See 57 FR at 45264.

⁴ In this proposal, the term “CBLR framework” refers to the simplified measure of capital adequacy provided in the CBLR NPR, as well as any subsequent changes to that proposal that are adopted during the rulemaking process.

⁵ As used in this NPR, the term “bank” is synonymous with the term “insured depository institution” as it is used in section 3(c)(2) of the FDI Act, 12 U.S.C. 1817(c)(2).

⁶ See 12 CFR 327.3(b)(1).

⁷ See 84 FR 3062 (February 8, 2019).

simplified measure of capital adequacy for qualifying community banking organizations, consistent with Section 201 of the Economic Growth, Regulatory Relief, and Consumer Protection Act (EGRRCPA or the Act).⁸ The Act defines a qualifying community banking organization as a depository institution or depository institution holding company with total consolidated assets of less than \$10 billion.⁹ In addition, the Act states that the Federal banking agencies may determine that a banking organization is not a qualifying community bank based on its risk profile.¹⁰ A qualifying community banking organization that reports a community bank leverage ratio, or CBLR (defined as the ratio of tangible equity capital to average total consolidated assets, both as reported on an institution's applicable regulatory filing), exceeding the level established by the Federal banking agencies of not less than 8 percent and not more than 10 percent would be considered well capitalized. The CBLR NPR proposed to define tangible equity capital (CBLR tangible equity) as total bank equity capital, prior to including minority interests, and excluding accumulated other comprehensive income (AOCI), deferred tax assets arising from net operating loss and tax credit carryforwards, goodwill, and certain other intangible assets, calculated in accordance with a qualifying community bank organization's regulatory reports.¹¹ The Federal banking agencies further proposed that qualifying community banking organizations¹² that elect to use the CBLR framework (CBLR banks) would report their CBLR and other relevant information on a simpler regulatory capital schedule in the Call Report, as opposed to the current schedule RC-R of the Call Report.¹³ Finally, under the

CBLR NPR, a CBLR bank must have a CBLR greater than 9 percent to be considered well capitalized.¹⁴ The Federal banking agencies also proposed proxy CBLR thresholds for the adequately capitalized, undercapitalized, and significantly undercapitalized PCA categories.¹⁵

In the interagency CBLR NPR, the Federal banking agencies noted that deposit insurance assessment regulations would be affected by the proposed CBLR framework.¹⁶ CBLR banks would no longer be required to calculate or report the components of regulatory capital used in the calculation of the tier 1 leverage ratio or risk-based capital, such as tier 1 capital or risk weighted assets.¹⁷

B. Use of Capital Measures in the Current Deposit Insurance Assessment System

Assessment Base

In 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) required that the FDIC amend its regulations to redefine the assessment base to equal average consolidated total assets minus average tangible equity.¹⁸ In implementing this requirement, the FDIC defined tangible equity as tier 1 capital, in part, because it minimized regulatory reporting.¹⁹ The FDIC also provides a deduction to the assessment base for custodial banks²⁰

using the Call Report as an example, as an indication of the potential reporting format and potential reporting burden relief for CBLR banks. See 84 FR at 3065 and 3074.

¹⁴ See 84 FR at 3064 and 3071. However, to be considered and treated as well capitalized under the CBLR framework, and consistent with the Federal banking agencies' current PCA rule, the qualifying community banking organization must demonstrate that it is not subject to any written agreement, order, capital directive, or prompt corrective action directive to meet and maintain a specific capital level for any capital measure. See 84 FR at 3064.

¹⁵ See 84 FR at 3071–72.

¹⁶ See 84 FR at 3073–74.

¹⁷ See 84 FR at 3073.

¹⁸ Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 331(b), 124 Stat. 1376, 1538 (codified at 12 U.S.C. 1817(note)).

¹⁹ See 76 FR 10673, 10678 (Feb. 25, 2011) (“Defining tangible equity as Tier 1 capital provides a clearly understood capital buffer for the DIF in the event of the institution's failure, while avoiding an increase in regulatory burden that a new definition of capital could cause.”).

²⁰ Generally, a custodial bank is defined as an IDI with previous calendar year-end trust assets (that is, fiduciary and custody and safekeeping assets, as reported on Schedule RC-T of the Call Report) of at least \$50 billion or those insured depository institutions that derived more than 50 percent of their revenue (interest income plus non-interest income) from trust activity over the previous calendar year. See 12 CFR 327.5(c)(1).

equal to a certain amount of low risk-weighted assets.²¹

In addition, the FDIC applies certain adjustments to a bank's assessment rate as part of the risk-based assessment system to better account for risk among banks based on their funding sources. The adjustments are calculated, in part, using a bank's assessment base. One adjustment, the depository institution debt adjustment (DIDA), is limited based on a bank's tier 1 capital.²²

Assessment Rate

Under the FDI Act, the FDIC has the authority to “establish separate risk-based assessment systems for large and small members of the Deposit Insurance Fund.”²³ Separate systems for large banks and small banks have been in place since 2007.²⁴ Assessment rates for established small banks²⁵ are calculated based on a formula that uses financial measures and a weighted average of supervisory ratings (CAMELS).²⁶ The financial measures are derived from a statistical model estimating the probability of failure over three years. The measures are shown in Table 1 below.

TABLE 1—FINANCIAL MEASURES USED TO DETERMINE ASSESSMENT RATES FOR ESTABLISHED SMALL BANKS

Financial measures
• Leverage Ratio.
• Net Income before Taxes/Total Assets.
• Nonperforming Loans and Leases/Gross Assets.
• Other Real Estate Owned/Gross Assets.
• Brokered Deposit Ratio.
• One Year Asset Growth.
• Loan Mix Index.

One of the measures, the Leverage Ratio, is defined as tier 1 capital divided by adjusted average assets (herein referred to as the tier 1 leverage ratio). The numerator and denominator of the Leverage Ratio are both based on the

²¹ The adjustment to the assessment base for banker's banks under 12 CFR 327.5(b) would not be affected by this proposal.

²² See 12 CFR 327.16(e)(2).

²³ 12 U.S.C. 1817(b)(1)(D).

²⁴ Under the assessment regulations, a “small institution” generally is an institution with less than \$10 billion in total assets, and a “large institution” generally is an institution with \$10 billion or more in total assets. See 12 CFR 327.8(e) and (f). A separate system for highly complex institutions has been in place since 2011. See 12 CFR 326.16(b)(2).

²⁵ Generally, an established institution is one that has been federally insured for at least five years. See 12 CFR 327.8(v).

²⁶ See 12 CFR 327.16(a)(1).

⁸ Public Law 115–174 (May 24, 2018).

⁹ See section 201(a)(3)(A) of the Act.

¹⁰ See section 201(a)(3)(B) of the Act.

¹¹ See 84 FR at 3068–69.

¹² In accordance with the Act, the Federal banking agencies propose to define a qualifying community bank generally as a depository institution or depository institution holding company with less than \$10 billion in total consolidated assets and that has limited amounts of off-balance sheet exposures, trading assets and liabilities, mortgage servicing assets, and certain deferred tax assets. An advanced approaches banking organization, including a subsidiary of a depository institution, bank holding company, or intermediate holding company that is an advanced approaches banking organization, would not be a qualifying community bank. See 84 FR at 3065–67.

¹³ In the CBLR NPR, the Federal banking agencies state that they intend to separately seek comment on the proposed changes to regulatory reports for qualifying community banking organizations that elect to use the CBLR framework; however, the CBLR NPR provides an illustrative reporting form,

definitions for the relevant PCA measure.²⁷

III. Summary of Proposal

Summary

In this NPR, the FDIC is proposing to apply the CBLR framework to the deposit insurance assessment system in a way that minimizes or eliminates any resulting increase in assessments that may arise without a change in risk and, to the fullest extent practicable, reduces regulatory reporting burden consistent with the objective of the CBLR framework, as discussed in the CBLR NPR.²⁸ As discussed more fully below, the FDIC is proposing to price all CBLR banks as small banks. The FDIC is also proposing to amend its assessment regulations to calculate the assessment base of CBLR banks using either CBLR tangible equity or tier 1 capital, and the assessment rate of established CBLR banks using the higher of either the CBLR or the tier 1 leverage ratio. For a minority of small banks, the use of the CBLR or CBLR tangible equity could result in a higher assessment rate or a larger assessment base, respectively. Therefore, through corresponding changes to the Call Report, the FDIC would propose to allow CBLR banks the option to use tier 1 capital in lieu of CBLR tangible equity when reporting “average tangible equity” on their Call Report, for purposes of calculating their assessment base. Through Call Report changes, CBLR banks also would have the option to report the tier 1 leverage ratio on Schedule RC–O of the Call Report, in addition to the CBLR on the simpler regulatory capital schedule under the CBLR framework, and the FDIC would apply the value that would result in the lower assessment rate (*i.e.*, the higher value). The FDIC, in coordination with the Federal Financial Institutions Examination Council (FFIEC), would seek comment on proposed changes to Schedule RC–O and its instructions in the Call Reports in a separate Paperwork Reduction Act notice that would align with the proposed amendments to the assessment regulations. This proposal meets the FDIC’s goal of extending the regulatory relief made available to small institutions under the proposed CBLR framework while minimizing or potentially eliminating increases in

deposit insurance assessments that are unrelated to a change in risk.

The FDIC, through this NPR, also proposes to clarify that a CBLR bank that meets the definition of a custodial bank would have no change to its custodial bank deduction or reporting items required to calculate the deduction. A CBLR bank that meets the definition of a custodial bank would continue to report items related to the custodial bank deduction on Schedule RC–O of the Call Report for assessment purposes, one of which is calculated based on the risk weighting of qualifying low-risk liquid assets; however, to utilize the deduction the bank would not be required to report the more detailed schedule of risk-weighted assets for regulatory capital purposes consistent with adoption of the CBLR framework. In addition, the proposal would clarify that the assessment regulations would continue to reference the PCA regulations for the definitions of capital categories for deposit insurance assessment purposes, including the proposed CBLR capital categories.

A. Assessment Base and Assessment Rate Adjustments

Tangible Equity

The FDIC is proposing to amend the definition of “tangible equity,” for purposes of calculating a CBLR bank’s average tangible equity and the assessment base, to mean either CBLR tangible equity or tier 1 capital.²⁹ For CBLR banks that do not elect the option, discussed below, to use tier 1 capital when reporting average tangible equity, CBLR tangible equity would be used to calculate the bank’s assessment base. All other banks would continue to use tier 1 capital when reporting average tangible equity, which the FDIC would use to calculate a bank’s assessment base.

The proposed change minimizes increases in deposit insurance assessments for CBLR banks that may arise without a change in risk. Based on Call Report data as of September 30, 2018, the FDIC estimates that for most, but not all, CBLR banks, CBLR tangible equity would equal or exceed tier 1 capital. However, in the event that a bank’s CBLR tangible equity is less than tier 1 capital, calculating a bank’s assessment base using CBLR tangible equity instead of tier 1 capital could result in a larger assessment base and a

higher assessment amount. Therefore, the FDIC is proposing to give CBLR banks the option to use either tier 1 capital or CBLR tangible equity when calculating “average tangible equity” for purposes of the bank’s assessment base calculation.³⁰ Banks currently report average tangible equity on item 5 of Schedule RC–O of their Call Report. Through changes to the Call Report, the FDIC would propose to retain this item, but amend the Call Report instructions to allow CBLR banks to report average tangible equity using either CBLR tangible equity or, if using tier 1 capital would result in a higher amount for average tangible equity (and subsequently a lower assessment base), the bank would have the option to use tier 1 capital.³¹ As discussed above, the FDIC, in coordination with the FFIEC, would seek comment on corresponding changes to Schedule RC–O and its instructions in a separate Paperwork Reduction Act notice.

The proposed change to “tangible equity” also maximizes regulatory relief for CBLR banks. A CBLR bank would experience a decrease in reporting burden as a result of this proposal. If the bank chooses the option to use tier 1 capital for assessment purposes, the bank would experience an increase in reporting burden relative to other CBLR banks by having to calculate tier 1 capital for purposes of reporting average tangible equity. Compared to current reporting, however, this would still result in an overall reduction in reporting, because the number of items reported by a CBLR bank that elects to use tier 1 capital for assessment purposes would not increase (tier 1 capital would be used in lieu of CBLR tangible equity in calculating and reporting “average tangible equity” on Schedule RC–O of its Call Report). The FDIC would continue to require all banks to maintain records required to verify the correctness of any assessment for three years from the due date of the assessment.³² The FDIC expects that a CBLR bank would only elect the option to use tier 1 capital if it would result in a lower assessment.

³⁰ All IDIs are instructed to calculate average tangible equity using the average of the three month-end balances within a quarter (monthly averaging). Some institutions with total consolidated assets of less than \$1 billion may report average tangible equity using an end-of-quarter balance. See 12 CFR 327.5(a)(2).

³¹ To illustrate the effect of using CBLR tangible equity or tier 1 capital on an IDI’s assessment, the FDIC plans to provide on its website an assessment estimation tool that banks can use to estimate deposit insurance assessment amounts under the proposal.

³² See 12 U.S.C. 1817(b)(4).

²⁷ See 12 CFR 327.16(a)(1)(ii).

²⁸ The changes proposed in this rulemaking do not apply to insured branches of foreign banks. These institutions file the FFIEC 002, which does not include many of the items, including capital measures, found in the Call Report schedules filed by other IDIs.

²⁹ As previously stated, the assessment base is equal to average consolidated total assets minus average tangible equity. This proposal would not change the calculation of average consolidated total assets as it relates to an IDI’s assessment base.

The proposed definition of “tangible equity” for purposes of calculating an IDI’s assessment base would affect adjustments that could apply to a CBLR bank’s initial base assessment rate because the assessment base is used in the denominator of each adjustment.³³ The FDIC expects that a CBLR bank would consider how the proposed change to “tangible equity” for purposes of calculating its assessment base could affect adjustments to its assessment rate when it makes its decision of whether to optionally report average tangible equity using tier 1 capital for deposit insurance assessment purposes. Thus, the FDIC does not propose any additional change to the assessment base as it is used for purposes of calculating the adjustments referenced above.

Question 1: The FDIC invites comment on providing a CBLR bank with the option to use tier 1 capital for purposes of reporting average tangible equity, which is used in the assessment base calculation. Is the proposed change appropriate? Should the FDIC only use CBLR tangible equity to calculate the assessment base of a CBLR bank, even if it could result in a higher assessment amount? Should CBLR banks be required to specify whether they are reporting tier 1 capital or CBLR tangible equity for assessments purposes in a separate line item of the Call Report? Should this option only stay in effect for a limited time to permit a transition to the new CBLR?

Depository Institution Debt Adjustment

The FDIC also proposes to amend the DIDA to incorporate CBLR tangible equity for CBLR banks. Under the proposal, the FDIC would exclude from the unsecured debt amount used in calculating the DIDA of a CBLR bank an amount equal to no more than 3 percent of CBLR tangible equity. For all other banks, the FDIC would continue to exclude an amount equal to no more than 3 percent of tier 1 capital, and thus those banks would see no change.³⁴ The

³³ For example, the unsecured debt adjustment applied to an IDI’s assessment rate equals the amount of long-term unsecured liabilities an IDI reports times the sum of 40 basis points plus the bank’s initial base assessment rate (that is, the assessment rate before any adjustments) divided by the assessment base. The other two adjustments affected by the proposed change to the definition of “tangible equity” for purposes of calculating an IDI’s assessment base are: the depository institution debt adjustment and the brokered deposit adjustment. See 12 CFR 327.16(e).

³⁴ The FDIC implemented the DIDA in a 2011 final rule to offset the benefit received by institutions that issue long-term, unsecured liabilities when these liabilities are held by another IDI. The exclusion of no more than 3 percent of tier

NPR would not change the 3 percent cap for the exclusion and would not require any change in reporting. For a CBLR bank, the FDIC would calculate the exclusion using end-of-quarter CBLR tangible equity, as reported in the simpler regulatory capital schedule under the CBLR framework. For a non-CBLR bank, the FDIC would continue to calculate the exclusion using end-of-quarter tier 1 capital, as reported in Schedule RC–R of the Call Report.

The FDIC is proposing to only use CBLR tangible equity for purposes of calculating the DIDA for CBLR banks because the adjustment currently applies to so few banks. Based on Call Report data as of September 30, 2018, 24 IDIs are subject to the DIDA and 22 of those could qualify as a CBLR bank. The majority of the 22 CBLR banks subject to the DIDA would experience little to no effect if the FDIC substitutes CBLR tangible equity for tier 1 capital. Based on the latest Call Report data, only 2 of the 22 CBLR banks subject to the DIDA would experience a change in their DIDA calculation, and the effect would be approximately \$1,500 per quarter. As such, the FDIC is proposing to substitute CBLR tangible equity, as reported on the simpler regulatory capital schedule under the CBLR framework, for tier 1 capital so that CBLR banks subject to the DIDA would not have to report tier 1 capital separately. The proposed change would extend the regulatory relief made available to small institutions under the proposed CBLR framework while minimizing increases to the DIDA that may arise without a corresponding increase to the debt issued by another IDI that is held by the bank.

Question 2: Should the FDIC allow CBLR banks to use either CBLR tangible equity or tier 1 capital for the DIDA calculation, whichever is highest? If so, should CBLR banks be required to report an additional line item for tier 1 capital?

Question 3: Should the FDIC use average tangible equity as a proxy for tier 1 capital for CBLR banks only, so that such banks do not have to report an additional line item for tier 1 capital? In this case, for CBLR banks only, the FDIC would use the amount reported in line item 5 of Schedule RC–O of their Call Report for the DIDA calculation in place of tier 1 capital.

B. Assessment Rates for Established Small Institutions

The FDIC is proposing to amend the definition of the Leverage Ratio in the small bank pricing methodology, which is used to calculate an established small

bank’s assessment rate, to mean the higher of either the CBLR or tier 1 leverage ratio, as applicable. For established CBLR banks, the CBLR would be used to calculate the bank’s assessment rate unless the bank opts to additionally report the tier 1 leverage ratio. For all other established small banks, the FDIC would continue to use the tier 1 leverage ratio to calculate an institution’s assessment rate. As discussed in more detail below, FDIC analysis suggests that substituting the CBLR for the current Leverage Ratio in the small bank pricing methodology would not materially change the predictive accuracy of the underlying statistical model used to determine assessment rates for established small banks.

The proposed change to “Leverage Ratio” minimizes increases in deposit insurance assessments that may arise without a change in risk. Based on Call Report data as of September 30, 2018, the FDIC estimates that for most, but not all, CBLR banks, the CBLR would equal or exceed the tier 1 leverage ratio and, therefore, would reduce or have no effect on an established small bank’s deposit insurance assessment rate. In the event that an established small bank’s CBLR is less than its tier 1 leverage ratio, however, calculating the bank’s assessment rate using the CBLR instead of the tier 1 leverage ratio could result in a higher assessment rate and a higher assessment amount.³⁵ Therefore, through upcoming Call Report changes, CBLR banks would have the option to separately report their tier 1 leverage ratio, in addition to the CBLR. As reflected in the proposed changes to the definition of “Leverage Ratio,” the FDIC would then use the higher value (i.e., the value that results in the lower assessment when calculating the institution’s assessment rate). To provide for this option in reporting, the FDIC, through changes to the Call Report, would retain and transfer item 44 from Schedule RC–R of the Call Report, to Schedule RC–O. A CBLR bank that elects to report its tier 1 leverage ratio for purposes of calculating its assessment rate would report that ratio on the item transferred to Schedule RC–O. A CBLR bank that does not elect to report the tier 1 leverage ratio would leave this item blank.³⁶ All CBLR banks

³⁵ To illustrate the effect of using the CBLR or tier 1 leverage ratio on an IDI’s assessment rate, the FDIC will provide on its website an assessment estimation tool that banks can use to estimate deposit insurance assessment rates under the proposal.

³⁶ By leaving this item blank, the FDIC would consider the value for the tier 1 leverage ratio to be

1 capital represents a de minimis amount of risk. See 76 FR at 10681.

would report their CBLR as part of the simpler capital schedule under the CBLR framework. As discussed above, to effectuate this option, the FDIC, in coordination with the FFIEC, would seek comment on corresponding changes to Schedule RC–O and its instructions in a separate Paperwork Reduction Act notice.

The proposed change to “Leverage Ratio” also maximizes regulatory relief for CBLR banks. A CBLR bank would experience a decrease in its reporting burden under the proposal. If the bank chooses the option to report the tier 1 leverage ratio for assessment purposes, the bank would experience an increase in reporting burden relative to other CBLR banks by having to calculate and report this additional line item on Schedule RC–O. The FDIC expects that a CBLR bank would only elect the option to calculate and report its tier 1 capital ratio if it would result in a lower assessment. A CBLR bank that elects to report its tier 1 leverage ratio would still benefit from the reduced reporting provided by the simpler regulatory capital schedule under the CBLR framework, relative to non-CBLR banks. All banks would continue to be required to maintain all records that the FDIC may require for verifying the correctness of any assessment for three years from the due date of the assessment.³⁷

Question 4: The FDIC invites comment on allowing a CBLR bank to additionally report the tier 1 leverage ratio to determine its deposit insurance assessment rate. Is the proposed change appropriate? Should the FDIC only use the CBLR to calculate the assessment rate of a CBLR bank, even if it could result in a higher assessment amount?

C. Pricing CBLR Banks as Small Institutions

The FDIC is proposing to amend the definition of “small institution” to include all banks that elect to adopt the CBLR framework, even if such a bank would otherwise be classified as a “large institution” under the assessment regulations.³⁸ This modification is necessary because otherwise the different eligibility thresholds used to define a small bank in assessment regulations and a CBLR bank under the

zero and the CBLR would be used to calculate a CBLR bank’s assessment rate because it would be the higher amount.

³⁷ See 12 U.S.C. 1817(b)(4).

³⁸ A CBLR bank that meets the definition of an established institution under 12 CFR 327.8(v), generally one that has been federally insured for at least five years, would be assessed as an established small bank. A CBLR bank that has been federally insured for less than five years would be assessed as a new small bank. See 12 CFR 327.8(w).

CBLR framework could result in a CBLR bank being assessed as a large bank.³⁹

For example, a substantial divestiture might cause a bank classified as large for the purpose of pricing deposit insurance to have less than \$10 billion in total consolidated assets in a particular quarter. Assuming that the bank meets the other criteria to be a qualifying community banking organization, the bank would be eligible to report under the CBLR framework beginning with the following quarter. Under existing assessment regulations, however, the bank would still be classified as a large institution until it reported total assets below \$10 billion for four consecutive quarters. Therefore, the bank could report the CBLR for regulatory capital purposes but, for a short period, it would continue to be priced as a large bank.

The proposed change to the assessment definition of “small institution” would prevent a scenario, such as the one described above, where a CBLR bank is priced as a large bank because it has not yet reported total assets below \$10 billion for four consecutive quarters. In addition, the FDIC also proposes to clarify that a CBLR bank with assets of between \$5 billion and \$10 billion cannot request to be treated as a large bank.⁴⁰ The FDIC believes that pricing a CBLR bank as a large bank would be inconsistent with the intention of the proposed CBLR framework to provide regulatory relief to small, community banks with a limited risk profile.⁴¹ The pricing methodology for large banks uses measures that are not reported by small banks and are meant to measure the risk of banks with more complex operations and organizational structures.⁴² Further, CBLR banks would no longer report the tier 1 leverage ratio or tier 1 capital, which are used for multiple measures in

³⁹ Under the current assessment regulations, a large bank is reclassified as small once it has reported less than \$10 billion in total assets for four consecutive quarters, and a small bank is reclassified as large once it has reported \$10 billion or more in total assets for four consecutive quarters. See 12 CFR 327.8(e). Under the CBLR NPR, a qualifying community banking organization is defined generally as a depository institution or depository institution holding company with less than \$10 billion in total consolidated assets at the end of the most recent quarter and that meet certain qualifying criteria. See 84 FR at 3065.

⁴⁰ Under current regulations, a bank with between \$5 billion and \$10 billion may request treatment as a large bank for deposit insurance assessments. See 12 CFR 327.16(f).

⁴¹ See 84 FR at 3067.

⁴² For example, the FDIC uses data on Schedule RC–O regarding higher-risk assets to calculate financial ratios used to determine a large or highly complex institution’s assessment rate, and small institutions are not required to report such information.

the large bank pricing methodology. Substituting the CBLR for the tier 1 leverage ratio or CBLR tangible equity for tier 1 capital in the large bank assessment methodology would require more extensive modifications to ensure that risk is priced appropriately.

Question 5: The FDIC invites comment on amending the definition of “small institution” to include CBLR banks. Are there limited instances where the FDIC should permit CBLR banks to be assessed as large institutions? If so, what are they and how should such institutions report the data necessary to be priced as a large bank (as determined under the assessment regulations)?

D. Clarifications Not Requiring a Substantive Change to Regulations

The FDIC, through this NPR, proposes to clarify that for any CBLR bank that meets the definition of a custodial bank there is no change in the reporting that is necessary to calculate and receive the custodial bank deduction under the assessment regulations. The NPR would not change the custodial bank deduction. A CBLR bank that also meets the definition of a custodial bank under the assessment regulations would continue to report items related to the custodial bank deduction on Schedule RC–O of the Call Report for assessment purposes, one of which is calculated based on the risk weighting of qualifying low-risk liquid assets. However, consistent with the CBLR framework, CBLR banks that meet the definition of a custodial bank would not be required to report the more detailed schedule of its risk-weighted assets for regulatory capital purposes in order to utilize the deduction.

In calculating the assessment base for custodial banks, the FDIC excludes a certain amount of low-risk assets, which are reported in Schedule RC–R of the Call Report, subject to the deduction limit.⁴³ Under the CBLR framework, these line items would not be included in the simpler regulatory capital schedule that would be filed by CBLR banks in the Call Report.⁴⁴ However, the FDIC is clarifying that it would not

⁴³ See 12 CFR 327.5(c)(2) (the FDIC will exclude from a custodial bank’s assessment base the daily or weekly average (depending on how the bank reports its average consolidated total assets) of all asset types described in the instructions to lines 1, 2, and 3 of Schedule RC of the Call Report with a standardized approach risk weight of 0 percent, regardless of maturity, plus 50 percent of those asset types described in the instructions to lines 1, 2, and 3 of Schedule RC of the Call Report, with a standardized approach risk-weight greater than 0 and up to and including 20 percent, regardless of maturity).

⁴⁴ See 84 FR at 3073.

require a custodial bank that elects to use the CBLR framework to separately report these items in order to continue utilizing the custodial bank deduction. A custodial bank would continue to report the numerical value of its custodial bank deduction and custodial bank deduction limit in Schedule RC–O of the Call Report. Also, the FDIC would require custodial banks to continue to maintain the proper documentation of their calculation for the custodial bank adjustment, and to make that documentation available upon request.⁴⁵

Question 6: The FDIC invites comment on allowing a custodial bank that is a CBLR bank to continue to utilize the custodial bank deduction by only reporting its custodial bank deduction and custodial bank limit on Schedule RC–O of its Call Report. Should such a bank be required to report additional items on the Call Report to support its calculation of the custodial bank deduction?

The FDIC also proposes to clarify that the assessment regulations would continue to reference the PCA regulations for the definitions of capital categories used in the deposit insurance assessment system. Capital categories for deposit insurance assessment purposes are defined by reference to the agencies' regulatory capital rules that would be amended under the CBLR NPR.⁴⁶ Any changes to the thresholds that are made as a result of the CBLR rulemaking process will be automatically incorporated into the assessment regulations. In the NPR, the FDIC also proposes to make technical amendments to the FDIC's assessment regulations to align with the changes in the CBLR NPR.

IV. Expected Effects

Based on Call Report data as of September 30, 2018, the FDIC does not expect that the proposed changes to the assessment regulations would have a material impact on aggregate assessment revenue or on rates paid by individual institutions. The FDIC estimates that 4,450 out of 5,477 IDIs (81.2 percent) would meet the proposed qualifying community banking organization criteria for the CBLR framework and would have a CBLR greater than 9 percent.⁴⁷ Of all banks, 4,479 (81.8

percent) would see no change in their deposit insurance assessment under the proposal.

Certain CBLR banks, however, could see a decrease or, potentially an increase, in their assessments under the proposal. A CBLR bank could experience a decreased assessment amount because its tier 1 capital is less than its CBLR tangible equity (resulting in a smaller assessment base and any applicable assessment adjustments) or because its tier 1 leverage ratio is lower than its CBLR (resulting in a higher Leverage Ratio and potentially a lower assessment rate). Conversely, a CBLR bank could experience an increased assessment amount if its tier 1 capital is greater than its CBLR tangible equity (resulting in a larger assessment base) or because its tier 1 leverage ratio is higher than its CBLR (resulting in a lower Leverage Ratio and potentially a higher assessment rate).

The FDIC estimates that the proposal would decrease assessments for 560 CBLR banks (10.2 percent of all banks). Of those, 458 (8.4 percent of all banks) would experience a decrease of less than 1 percent, and 40 (0.7 percent of all banks) would experience a decrease greater than 5 percent. On the other hand, the proposal could also result in increased assessments for 438 banks (8.0 percent of all banks). Of those, 347 (6.3 percent of all banks) could experience an increase of less than 1 percent, and 22 (0.4 percent of all banks) could experience an increase greater than 5 percent. CBLR banks facing an increase in assessments would have the option of avoiding that increase by using tier 1 capital for the assessment base calculation, reporting the tier 1 leverage ratio for the assessment rate calculation, or both. Therefore, the number of banks that would experience an increase in assessments as the result of this proposal is likely to be less than 438, depending on the number of banks that utilize the options.

If all CBLR banks that could experience an increase in assessments by opting into the CBLR framework choose to use tier 1 capital for the assessment base calculation and the tier 1 leverage ratio for the assessment rate calculation (in order to prevent an increase in assessments), and assessments for the remaining CBLR banks are determined using CBLR tangible equity and the CBLR, the FDIC estimates that aggregate revenue to the DIF would decline by \$4.3 million annually (0.08% of annual assessments),

changes in the number of institutions and to relevant Call Report data and was not the result of any change to the proposed qualifying criteria.

based on Call Report data as of September 30, 2018.

Based on Call Report data as of September 30, 2018, five custodial banks would meet the definition of a "qualifying community banking organization" under the CBLR NPR. Under the proposal, a custodial bank that is a CBLR bank would be able to continue to report the custodial bank deduction for its assessment base and would be able to report the simpler regulatory capital schedule proposed under the CBLR NPR. All five custodial banks that would meet the definition of a "qualifying community banking organization" would see no change to their assessments.

The relatively small change in aggregate deposit insurance assessment revenue suggests that substituting the CBLR for the tier 1 leverage ratio, as proposed, would have minimal impact on the FDIC's ability to fairly and adequately price a bank's risk to the DIF. The FDIC further evaluated this claim by performing out-of-sample backtesting to compare the accuracy ratio⁴⁸ of a model that uses the CBLR to the accuracy ratio of the current model that uses the tier 1 leverage ratio.

The backtests show that substituting the CBLR for the tier 1 leverage ratio would not materially change the predictive accuracy of the underlying statistical model used to determine assessment rates for established small banks. To make this point, the table below compares the accuracy ratios of the statistical model using a close approximation of the CBLR in lieu of the tier 1 leverage ratio (column A) with the current model using the tier 1 leverage ratio (column B).⁴⁹ Column A shows that the resulting accuracy ratio when substituting the CBLR for the tier 1 leverage ratio is 0.646. Column B shows that the current small bank assessment system basically performed

⁴⁸ Briefly, an accuracy ratio is a number between 0 and 1 (inclusive) that measures how well the model performs a correct rank-ordering of banks that failed over the projection horizon. A "perfect" model is one that always assigns a higher probability of failure to a bank that subsequently failed in the projection horizon compared to a bank that does not fail; such a model receives an accuracy ratio of 1. At the other extreme, a model that performs no better than random guessing would receive an accuracy ratio of 0. A technical explanation of an accuracy ratio can be found at 81 FR 6127–28 (Feb. 4, 2016).

⁴⁹ The substitution of the CBLR for the tier 1 leverage ratio is made only for cases in which the bank is estimated to meet the definition of a qualifying community bank organization. Regressions were done on an out-of-sample basis. For example, the backtest from the first row is based on parameter estimates based on data from 2003 and earlier. Then the projection is made using data available at the end of 2006 to make projections over the next three years.

⁴⁵ See 12 U.S.C. 1817(b)(4).

⁴⁶ See 12 CFR 327.8(z).

⁴⁷ In the CBLR NPR, the Federal banking agencies estimated that 4,469 IDIs met all of the proposed qualifying criteria, as of June 30, 2018. See 84 FR at 3072. The estimate of 4,450 qualifying community banking organizations in this NPR is based on data as of September 30, 2018. The difference of 19 institutions is attributable to

the same, with an accuracy ratio of 0.645. Similar backtests are repeated for other years with the average accuracy ratio for all of the backtests virtually the same between a model that uses the

CBLR in lieu of the tier 1 leverage ratio and a model that reflects the current small bank assessment system. These results provide a strong case that substituting the CBLR for the tier 1

leverage ratio has little impact on predictive accuracy of the underlying model used to determine assessments for established small banks.

TABLE 2—ACCURACY RATIO COMPARISON BETWEEN THE PROPOSED RULE AND THE CURRENT SMALL BANK DEPOSIT INSURANCE ASSESSMENT SYSTEM

Year of projection	Accuracy ratio for the proposal *	Accuracy ratio for the current small bank assessment system	Accuracy ratio for the proposal—accuracy ratio for the current system
	(A)	(B)	(A – B)
2006	0.646	0.645	0.001
2007	0.746–0.754	0.748	(0.002)–0.006
2008	0.910–0.912	0.910	0.000–0.002
2009	0.937–0.938	0.938	0.000–0.001
2010	0.969	0.969	0.000
2011	0.952–0.953	0.953	(0.001)–0.000
2012	0.917–0.919	0.918	(0.001)–0.001
2013	0.958–0.960	0.960	(0.002)–0.000
2014	0.879–0.887	0.889	(0.010)–(0.002)
2015	0.857	0.857	0.000
Average	0.877–0.879	0.879	(0.002)–0.000

Note: Table only includes institutions with less than \$10 billion in assets that filed a Call Report. Thus, for projections made from 2011 and earlier, Thrift Financial Report filers are excluded.

* Data necessary to calculate the CBLR, as defined in the CBLR rule, are not available prior to 2015 (except for a small number of banks in 2014). Instead, the FDIC used two alternative capital ratio definitions that are upper and lower bounds of the CBLR in over 99 percent of cases. Column (A) reflects a range of estimates of accuracy ratios for the proposal based on those two alternative capital ratio definitions.

** The difference uses the midpoint of the range in column (A).

Question 7: The FDIC invites comments on all aspects of the information provided in this Expected Effects section. In particular, would this proposal have any significant effects on institutions that the FDIC has not identified?

V. Alternatives

The FDIC considered the reasonable and possible alternatives described below. On balance, the FDIC believes the current proposal would meet its stated policy objectives in the most appropriate and straightforward manner.

One alternative would be to leave in place the current assessment regulations and require CBLR banks to report all of the necessary data related to tier 1 capital and the tier 1 leverage ratio, to determine the bank’s assessment base and rate. In other words, the FDIC would not incorporate CBLR tangible equity or the CBLR into the current assessment regulations and require CBLR banks to report all of the necessary data related to tier 1 capital and the tier 1 leverage ratio, to determine an institution’s assessment base and rate. This option, however, would not accomplish the policy objective of aligning with the CBLR framework to reduce regulatory reporting burden for small institutions.

The FDIC could also require all CBLR banks to use CBLR tangible equity and

the CBLR, as appropriate, for determining deposit insurance assessments, either without the option to use tier 1 capital or report the tier 1 leverage ratio if it resulted in a lower deposit insurance assessment, or with a time limit on a bank’s ability to elect that option. This alternative would be easy to understand and implement, but it would raise costs for some banks and, therefore, would fail to meet the policy objective of minimizing increases in deposit insurance assessments for some banks with no corresponding change in their risk profile.

Under a third alternative, the FDIC could use historical data to estimate each CBLR bank’s assessment amount based on the CBLR framework and compare this estimate to the bank’s assessment amount based on tier 1 capital and the tier 1 leverage ratio. For CBLR banks that are expected to experience an assessment increase, the FDIC could estimate the amount of the increase using historical data and reduce the bank’s assessment by the estimated increase for one year. This alternative would temporarily eliminate the unintended consequence of higher assessments for banks with no change in risk profile, but the estimates would only be valid for the historical quarter estimated and the relationship between the estimate and the actual amount would likely become less accurate over

time. At the conclusion of the one year period, a CBLR bank may continue to experience a higher assessment, but would no longer receive an assessment reduction and would have no other option to offset that increase other than to alter its risk profile. Finally, this alternative would also be operationally complex, particularly in comparison to the current proposal, which the FDIC believes would achieve a similar result in a more straightforward manner.

Question 8: The FDIC invites comment on the reasonable and possible alternatives described in this proposed rule. Should the FDIC consider other reasonable and possible alternatives?

VI. Request for Comments

In addition to its request for comment on specific parts of the proposal, the FDIC seeks comment on all aspects of this proposed rulemaking.

VII. Effective Date

The effective date of amendments to the assessment regulations that accommodate reduced reporting under the CBLR framework would coincide with the effective date of a final rule establishing the CBLR framework, but is not expected to occur prior to September 30, 2019.

VIII. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act⁵⁰ requires the Federal banking agencies to use plain language in all proposed final rules published after January 1, 2000. The FDIC has sought to present the proposed regulation in a simple and straightforward manner, and invites your comments on how to make this proposal easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could the material be better organized?
- Are the requirements in the proposed regulation clearly stated? If not, how could the regulation be stated more clearly?
- Does the proposed regulation contain language or jargon that is unclear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand?

IX. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, generally requires an agency, in connection with a proposed rule, to prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities.⁵¹ However, a regulatory flexibility analysis is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined “small entities” to include banking organizations with total assets of less than or equal to \$550 million.⁵² Certain types of rules, such as rules of particular applicability relating to rates, corporate or financial structures, or practices relating to such rates or structures, are expressly excluded from the definition of “rule” for purposes of

the RFA.⁵³ Because the proposed rule relates directly to the rates imposed on IDIs for deposit insurance and to the deposit insurance assessment system that measures risk and determines each bank’s assessment rate, the proposed rule is not subject to the RFA. Nonetheless, the FDIC is voluntarily presenting information in this RFA section.

As of June 30, 2018—the most recent period for which full data on small entities is available—there were 4,062 FDIC-insured depository institutions considered to be small entities for the purposes of RFA.⁵⁴ Of these, 3,450 (84.9 percent) institutions are currently eligible to use the CBLR. The proposed rule could affect deposit insurance assessments for these FDIC-insured small entities, but as explained below, these effects are likely to be small.

Using data from the Call Report as of September 30, 2018, the FDIC calculated that 2,870 small, FDIC-insured institutions (83.2 percent) are unlikely to experience a change in their assessments because of this rule. The FDIC estimates that 378 small, FDIC-insured institutions (11.0 percent) are likely to experience a decrease in their assessments under the proposal; however 305 of these (7.5 percent) are likely to see assessments reduced by less than one percent. Only 30 small institutions (0.7 percent) are likely to see their assessments reduced by more than five percent. The FDIC estimates that 202 small, FDIC-insured institutions (5.9 percent) could experience an increase in their assessments under the proposal. However, since the proposal allows banks the option to report tier 1 capital or the tier 1 leverage ratio if it results in a lower assessment, the FDIC presumes that none of these banks would choose higher assessments.

The proposed changes would not require any additional reporting, unless a CBLR bank chooses the option to report its tier 1 leverage ratio to calculate its assessment rate or use tier 1 capital in the calculation of its assessment base. The FDIC expects that a CBLR bank would only elect to use tier 1 capital or the tier 1 leverage ratio if it would result in a lower assessment.

The proposed rule could pose some additional regulatory costs for covered institutions associated with changes to internal systems or processes, or changes to reporting requirements.

However, the FDIC believes that these additional costs are likely to be de minimis because the banks likely already collect and report the data that would be used in revised calculations. Banks opting to report the tier 1 leverage ratio on Schedule RC–O would have an offsetting reduction in burden from no longer reporting the current Schedules RC–R and would benefit from a lower assessment than it would have using the CBLR.

Question 9: The FDIC invites comments on all aspects of the supporting information provided in this RFA section. In particular, would this rule have any significant effects on small entities that the FDIC has not identified?

X. Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA) of 1995,⁵⁵ the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently-valid Office of Management and Budget (OMB) control number. The FDIC’s OMB control numbers for its assessment regulations are 3064–0057, 3064–0151, and 3064–0179. The proposed rule does not revise any of these existing assessment information collections pursuant to the PRA and consequently, no submissions in connection with these OMB control numbers will be made to the OMB for review. However, the proposed rule will require changes to Schedule RC–O of the Call Reports (FFIEC 031, FFIEC 041, and FFIEC 051 (OMB No. 3064–0052 (FDIC), 7100–0036 (Federal Reserve System) and 1557–0081 (Office of the Comptroller of the Currency)), which will be coordinated by the Federal Financial Institutions Examination Council and addressed in a separate **Federal Register** notice.

XI. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),⁵⁶ in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions, each Federal banking agency must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such

⁵⁰ Public Law 106–102, sec. 722, 113 Stat. 1338, 1471 (1999).

⁵¹ 5 U.S.C. 601 *et seq.*

⁵² The SBA defines a small banking organization as having \$550 million or less in assets, where “a financial institution’s assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.” See 13 CFR 121.201 (as amended, effective December 2, 2014). “SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.” See 13 CFR 121.103. Following these regulations, the FDIC uses a covered entity’s affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the covered entity is “small” for the purposes of RFA.

⁵³ 5 U.S.C. 601.

⁵⁴ This is the latest date for which data from bank holding company financial reports (Y–9C) is available for determining which banks are small under the SBA definition.

⁵⁵ 44 U.S.C. 3501 *et seq.*

⁵⁶ 12 U.S.C. 4802(a).

regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on insured depository institutions generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.⁵⁷

The FDIC notes that comment on these matters has been solicited in other sections of this **SUPPLEMENTARY INFORMATION** section, and that the requirements of RCDRIA will be considered as part of the overall rulemaking process. In addition, FDIC invites any other comments that further will inform the FDIC's consideration of RCDRIA.

List of Subjects in 12 CFR Part 327

Bank deposit insurance, Banks, Banking, Savings associations.

Authority and Issuance

For the reasons set forth above, the FDIC proposes to amend part 327 of title 12 of the Code of Federal Regulations as follows:

PART 327—ASSESSMENTS

■ 1. The authority for 12 CFR part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

■ 2. In § 327.5 revise paragraphs (a)(2) and (a)(2)(iii) to read as follows:

§ 327.5 Assessment base.

- (a) * * *
- (1) * * *

(2) *Average tangible equity defined and calculated.* Average tangible equity is defined as tangible equity using either the monthly averaging or quarter-end averaging in paragraphs (a)(2)(i) or (ii) of this section, as applicable. Tangible equity is defined as Tier 1 capital, except that in the case of a qualifying

community banking organization that elects to use the community bank leverage ratio framework under 12 CFR 3.12(a)(3), 12 CFR 217.12(a)(3), or 12 CFR 324.12(a)(3), tangible equity is defined as Tier 1 capital or CBLR tangible equity as defined in 12 CFR 3.12(b)(2), 12 CFR 217.12(b)(2), and 12 CFR 324.12(b)(2).

- (i) * * *
- (ii) * * *

(iii) *Calculation of average tangible equity for the surviving institution in a merger or consolidation.* For the surviving institution in a merger or consolidation, tangible equity shall be calculated as if the merger occurred on the first day of the quarter in which the merger or consolidation occurred.

* * * * *

■ 3. Revise § 327.6, paragraph (b) to read as follows:

§ 327.6 Mergers and consolidations; other terminations of insurance.

* * * * *

(b) *Assessment for quarter in which the merger or consolidation occurs.* For an assessment period in which a merger or consolidation occurs, consolidated total assets for the surviving or resulting institution shall include the consolidated total assets of all insured depository institutions that are parties to the merger or consolidation as if the merger or consolidation occurred on the first day of the assessment period. Tangible equity shall be reported in the same manner.

* * * * *

■ 4. Revise § 327.8, paragraphs (e) and (z) to read as follows:

§ 327.8 Definitions.

* * * * *

(e) *Small institution.* An insured depository institution with assets of less than \$10 billion as of December 31, 2006, and an insured branch of a foreign institution shall be classified as a small institution. If, after December 31, 2006, an institution classified as large under paragraph (f) of this section (other than an institution classified as large for purposes of §§ 327.9(e) and 327.16(f)) reports assets of less than \$10 billion in

its quarterly reports of condition for four consecutive quarters, the FDIC will reclassify the institution as small beginning the following quarter. An insured depository institution that elects to use the community bank leverage ratio framework under 12 CFR 3.12(a)(3), 12 CFR 217.12(a)(3), or 12 CFR 324.12(a)(3) shall be classified as a small institution, even if that institution otherwise would be classified as a large institution under paragraph (f) of this section.

* * * * *

(z) *Well capitalized, adequately capitalized and undercapitalized.* For any insured depository institution other than an insured branch of a foreign bank, Well Capitalized, Adequately Capitalized and Undercapitalized have the same meaning as in: 12 CFR 6.4 (for national banks and federal savings associations), as either may be amended from time to time, except that 12 CFR 6.4(b)(1)(E) and (e), as they may be amended from time to time, shall not apply; 12 CFR 208.43 (for state member institutions), as either may be amended from time to time, except that 12 CFR 208.43(b)(1)(E) and (c), as they may be amended from time to time, shall not apply; and 12 CFR 324.403 (for state nonmember institutions and state savings associations), as either may be amended from time to time, except that 12 CFR 324.403(b)(1)(E) and (d), as they may be amended from time to time, shall not apply.

■ 5. Revise the table under § 327.16, paragraph (a)(1)(ii)(A) to read as follows:

§ 327.16 Assessment pricing methods—beginning the first assessment period after June 30, 2016, where the reserve ratio of the DIF as of the end of the prior assessment period has reached or exceeded 1.15 percent.

- (a) * * *
- (1) * * *
- (i) * * *

(ii) *Definitions of measures used in the financial ratios method—(A) Definitions.* The following table lists and defines the measures used in the financial ratios method:

DEFINITIONS OF MEASURES USED IN THE FINANCIAL RATIOS METHOD

Variables	Description
Leverage Ratio (%)	The Leverage Ratio means Tier 1 capital divided by adjusted average assets (numerator and denominator are both based on the definition for prompt corrective action). In the case of a qualifying community banking organization that elects to use the community bank leverage ratio framework under 12 CFR 3.12(a)(3), 12 CFR 217.12(a)(3), or 12 CFR 324.12(a)(3), the Leverage Ratio means the higher of: Tier 1 capital divided by adjusted average assets (numerator and denominator are both based on the definition for prompt corrective action); or CBLR tangible equity divided by average total consolidated assets (numerator and denominator are both based on the definition for prompt corrective action, as applicable).

⁵⁷ Id.

DEFINITIONS OF MEASURES USED IN THE FINANCIAL RATIOS METHOD—Continued

Variables	Description
Net Income before Taxes/ Total Assets (%).	Income (before applicable income taxes and discontinued operations) for the most recent twelve months divided by total assets. ¹
Nonperforming Loans and Leases/Gross Assets (%).	Sum of total loans and lease financing receivables past due 90 or more days and still accruing interest and total nonaccrual loans and lease financing receivables (excluding, in both cases, the maximum amount recoverable from the U.S. Government, its agencies or government-sponsored enterprises, under guarantee or insurance provisions) divided by gross assets. ²
Other Real Estate Owned/ Gross Assets (%).	Other real estate owned divided by gross assets. ²
Brokered Deposit Ratio	The ratio of the difference between brokered deposits and 10 percent of total assets to total assets. For institutions that are well capitalized and have a CAMELS composite rating of 1 or 2, reciprocal deposits are deducted from brokered deposits. If the ratio is less than zero, the value is set to zero.
Weighted Average of C, A, M, E, L, and S Component Ratings.	The weighted sum of the “C,” “A,” “M,” “E,” “L,” and “S” CAMELS components, with weights of 25 percent each for the “C” and “M” components, 20 percent for the “A” component, and 10 percent each for the “E,” “L,” and “S” components.
Loan Mix Index	A measure of credit risk described paragraph (a)(1)(ii)(B) of this section.
One-Year Asset Growth (%)	Growth in assets (adjusted for mergers ³) over the previous year in excess of 10 percent. ⁴ If growth is less than 10 percent, the value is set to zero.

¹ The ratio of Net Income before Taxes to Total Assets is bounded below by (and cannot be less than) –25 percent and is bounded above by (and cannot exceed) 3 percent.
² Gross assets are total assets plus the allowance for loan and lease financing receivable losses (ALLL).
³ Growth in assets is also adjusted for acquisitions of failed banks.
⁴ The maximum value of the Asset Growth measure is 230 percent; that is, asset growth (merger adjusted) over the previous year in excess of 240 percent (230 percentage points in excess of the 10 percent threshold) will not further increase a bank’s assessment rate.

* * * * *

■ 6. Revise § 327.16, paragraph (e)(2)(i) to read as follows:

§ 327.16 Assessment pricing methods—beginning the first assessment period after June 30, 2016, where the reserve ratio of the DIF as of the end of the prior assessment period has reached or exceeded 1.15 percent.

* * * * *

(e) * * *

(2) * * *

(i) *Application of depository institution debt adjustment.* An insured depository institution shall pay a 50 basis point adjustment on the amount of unsecured debt it holds that was issued by another insured depository institution to the extent that such debt exceeds 3 percent of the institution’s Tier 1 capital or, in the case of a qualifying community banking organization that elects to use the community bank leverage ratio framework under 12 CFR 3.12(a)(3), 12 CFR 217.12(a)(3), or 12 CFR 324.12(a)(3), CBLR tangible equity as defined in 12 CFR 3.12(b)(2), 12 CFR 217.12(b)(2), or 12 CFR 324.12(b)(2), as applicable. The amount of long-term unsecured debt issued by another insured depository institution shall be calculated using the same valuation methodology used to calculate the amount of such debt for reporting on the asset side of the balance sheets.

* * * * *

Dated at Washington, DC, on December 18, 2018.
 By order of the Board of Directors.

Federal Deposit Insurance Corporation.
Robert E. Feldman,
Executive Secretary.
 [FR Doc. 2019–02761 Filed 2–20–19; 8:45 am]
 BILLING CODE 6714–01–P

FARM CREDIT ADMINISTRATION
12 CFR Part 614
RIN 3052–AD32

Advance Notice of Proposed Rulemaking—Young, Beginning, and Small Farmers and Ranchers

AGENCY: Farm Credit Administration.
ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Farm Credit Administration (FCA, Agency, we, our) is requesting comments on ways to collect, evaluate, and report data on how the Farm Credit System (FCS or System) is fulfilling its mission to finance and provide services to young, beginning, and small (YBS) farmers, ranchers, and producers or harvesters of aquatic products (YBS Farmer(s)). Additionally, we are seeking comments on how FCA should define or clarify key terms associated with the collection and reporting of YBS data.

DATES: You may send comments on or before May 22, 2019.

ADDRESSES: We offer a variety of methods for you to submit comments on this advance notice of proposed rulemaking (ANPRM). For accuracy and efficiency reasons, commenters are encouraged to submit comments by

email or through the Agency’s website. As facsimiles (fax) are difficult for us to process and achieve compliance with section 508 of the Rehabilitation Act, we are no longer accepting comments submitted by fax. Regardless of the method you use, please do not submit your comment multiple times via different methods. You may submit comments by any of the following methods:

- *Email:* Send us an email at regcomm@fca.gov.
- *FCA website:* <https://www.fca.gov/>. Click inside the “I want to . . .” field near the top of the page; select “comment on a pending regulation” from the dropdown menu; and click “Go.”
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Barry F. Mardock, Deputy Director, Office of Regulatory Policy, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102–5090.

You may review copies of all comments we receive at our office in McLean, Virginia, or on our website at <http://www.fca.gov>. Once you are in the website, click inside the “I want to . . .” field near the top of the page; select “find comment on pending regulation” from the dropdown menu; and click “Go.” We will show your comments as submitted, but for technical reasons we may omit items such as logos and special characters. Identifying information that you provide, such as phone numbers and addresses, will be publicly available. However, we will attempt to remove

email addresses to help reduce internet spam.

FOR FURTHER INFORMATION CONTACT:

Salvatore Iannetta, Office of Regulatory Policy, (703) 883-4326, David Grahn, Office of General Counsel, (703) 883-4145, TTY (703) 883-4056, Farm Credit Administration, 1501 Farm Credit Drive, McLean, VA 22102-5090.

SUPPLEMENTARY INFORMATION:

I. Objective

The purpose of this ANPRM is to gather public input on how FCA might:

- Improve the accuracy, transparency, and process by which FCA ensures that YBS Farmer data is properly collected and reported by the FCS.
- Clarify the definitions of terms related to the collection, reporting, and identification of YBS Farmer data.
- Ensure the definitions of YBS Farmers and related terms remain relevant and reflective of the evolving agricultural economy.
- Evaluate the effectiveness of each FCS institution's YBS program to achieve its mission of serving YBS Farmers.

II. Background

The Farm Credit Act of 1971, as amended (Act), requires each System association to prepare a program for furnishing sound and constructive credit and related services to YBS Farmers. Annually, each district bank reports to FCA on the operations and achievements by the associations under the YBS programs. We provide a summary and analysis of the results in our annual report to Congress on the condition of the System. We are reviewing the methods used to collect and report YBS data to ensure that it is accurate, complete, and can be used reliably in conjunction with other related data reported by the System. As part of our review, we are seeking comments on methods and practices that could be used to improve the collection and reporting of YBS Farmer data and the oversight of such.

The Act¹ authorizes the FCS² to provide financing and services to farmers and ranchers across the country and Puerto Rico through FCS banks and associations (collectively referred to as "Institutions"). The Act also provides FCA, an independent agency in the executive branch of the Government, authority to regulate and examine these

Institutions.³ The System is organized around four banks that each supervise and provide funding to associations within each bank's district. Except for the authority of CoBank, ACB, to finance and provide services to agricultural cooperatives under title III of the Act, agricultural lending and other related services are provided primarily through the associations.⁴

In establishing the FCS as a government sponsored enterprise, Congress provided farmers and ranchers with an option of obtaining financing through borrower-owned cooperatives that give them the ability to participate in the ownership, management, and control of their lender and to ensure that a source of financing dedicated to their needs remains available.⁵ One of the specific Congressionally required responsibilities of the System is provided in section 4.19 of the Act (12 U.S.C. 2207), which requires FCS associations to have a program "for furnishing sound and constructive credit and related services to young, beginning, and small farmers and ranchers".⁶ In addition, this section requires that FCS banks report annually to FCA about the operations and achievements of the associations' lending and service programs for YBS Farmers.⁷ FCA's regulations that implement these requirements are located at 12 CFR 614.4165. FCA prepares an annual report on the quantitative and qualitative results achieved by the System and submits this information to Congress when FCA submits its annual report on the condition of the System. FCA has provided guidance and clarification on the System's YBS mission responsibilities through booklet (BL) 040 Revised—Providing Sound and Constructive Credit to Young, Beginning, and Small Farmers, Ranchers, and Producers or Harvesters of Aquatic Products⁸ and annual call reporting instructions. BL-040 Revised provides the definition for each category of YBS Farmers. As stated in the booklet, the three categories are separate and distinct, and a loan to one borrower may meet the definition for

any or all of the categories, but a loan does not have to meet all three to be considered a loan to a YBS Farmer.

III. Potential Areas for Improvement

Reconciling YBS data can be challenging. The current reporting practices count the number of transactions and volume of commitments for System Institutions that involve YBS Farmers. This approach identifies the overall System dollars committed to YBS Farmers based on technology/data/standards primarily developed in the 1990s. The goal is to improve upon this approach and provide more granularity for reporting and tracking. For example, a farmer can meet the requirements for both a young and beginning farmer. Under the current approach and direction for reporting, this farmer's data would be separately counted and reported in both the young and beginning categories. This situation can be compounded because more than one Institution may be participating in the financing of an individual YBS Farmer, which allows each participation interest to be counted and leads to further duplication when the Institutions' numbers are consolidated.

Due to the unique nature of this data, some banks' and associations' collection and reporting processes require considerable manual review and adjustment after retrieval from the core accounting systems. This situation creates difficulty in aligning YBS Farmer data with other data sources and reports generated from the Institutions' core accounting systems. Finally, after recent analysis of the YBS collection and reporting practices of several banks and associations, more guidance is needed to ensure more uniform and efficient collection and reporting of YBS Farmer data.

The definitions for the YBS categories have virtually remained the same since 1998, and other agricultural data sources have similar, but not equivalent, definitions. For example, since 1998, a farmer falls within the "small" category if the farmer "normally generates less than \$250,000 in annual gross sales of agricultural or aquatic products". Several agricultural and economic cycles have occurred since 1998, and we are considering whether the \$250,000 gross sales amount continues to be appropriate or should be revised or indexed to reflect the changes, including the economic conditions presently affecting agricultural producers. In addition to these challenges, several recent mergers of FCS associations have resulted in

³ See sections 5.7 and 5.9 of the Act (12 U.S.C. 2241 and 2243).

⁴ CoBank, pursuant to title III of the Act, also has authority to provide financing to certain rural utilities projects. More detailed information on the structure of the FCS can be found on at <https://www.fca.gov/>.

⁵ See section 1.1 of the Act (12 U.S.C. 2001).

⁶ See, section 4.19(a) of the Act (12 U.S.C. 2207(a)).

⁷ See, section 4.19(b) of the Act (12 U.S.C. 2207(b)).

⁸ BL-040 can be found at: FCA website—Bookletters.

¹ See, 12 U.S.C. 2001 *et seq.*

² The System is comprised of borrower-owned banks, associations, and service entities that collectively provide financing and other services to support agriculture and agriculture related operations as well as certain related industries that support U.S. agriculture.

unexpected variability in the YBS data reported to FCA from the banks.

Based on the forgoing, FCA is considering whether changes to our YBS regulations are appropriate or needed.

IV. Request for Comments

We request and encourage any interested person(s) to submit comments on the following questions and ask that you support your comments with relevant data or examples. We remind commenters that comments, and data submitted in support of a comment, will be available to the public through our website.

We have organized our questions into the following categories: Reporting of YBS Farmer data and definitions of key terms associated with YBS Farmer data.

A. Reporting of YBS Farmer Data

As described above, FCA requires each FCS bank to obtain reports on the activities for YBS Farmer programs from the associations under its supervision. These annual reports summarize the operations and achievements of the YBS Farmer programs in each district. The banks then provide loan information for YBS Farmers to FCA, and we include a summary and analysis of the information in our annual report to Congress.

The reporting period for gross new YBS lending is the calendar year. Outstanding YBS loans include all loans designated as YBS currently on the books as of December 31st in the reporting year. Because the YBS mission is focused on each borrower group separately, data are reported separately for each of the three YBS borrower categories. Since some loans fit within more than one category, adding the loans across categories cannot be done to accurately measure of the System's YBS lending involvement. As such, we are seeking comment on the following questions to determine if the current reporting structure is sufficient to determine and report the FCS's activities that support Section 4.19 of the Act:

1. Should loans continue to be reported in all the existing categories in which they fit? Alternatively, should loans be reported in seven mutually exclusive categories: Young; beginning; small; young and small; young and beginning; beginning and small; and young, beginning, and small?

2. When reporting YBS Farmer program performance, which would be more useful, a focus on the dollar volume of loans, the number of loans, the number of YBS Farmers that received credit and services, a combination of these, or all?

3. Under FCA's regulations, the term "services," as used in section 4.19(a) of the Act, includes leases and related services made by System banks and direct lender associations under titles I or II authorities. As such, how appropriate is it for lease activity to be reported for YBS purposes? Should leases and services be reported together with or separately from loans?

The preamble to FCA's Final Rule on YBS Farmers (12 CFR 614.4165)⁹ stated the objective for the rule is to ensure that the System provides sound and constructive credit and services to YBS farmers and ranchers through: Clear, meaningful, and results-oriented guidelines for System YBS policies and programs; and enhanced reporting and disclosure to the public on the System's performance and compliance with its statutory YBS mission. To evaluate this objective further, we are seeking comment to determine if there is additional information we should collect to better measure the System's performance in fulfilling its YBS mission.

4. What additional elements or measurements would be useful in determining the FCS's compliance with and mission performance under section 4.19 of the Act and FCA regulations at 12 CFR 614.4165?

5. What are ways Institutions could pool resources to ensure all eligible YBS Farmers are being served?

6. In what ways could Institutions use investment authorities to assist YBS Farmers, and should such investments be reported separately from YBS Farmer loan data?

B. Definitions of Key Terms Associated With YBS Farmer Data

FCA defines Young, Beginning, and Small farmers in Bookletter 040—Revised "Providing Sound and Constructive Credit to Young, Beginning, and Small Farmers, Ranchers, and Producers or Harvesters of Aquatic Products". These definitions have virtually remained the same since 1998. Additionally, the categories remain separate and distinct. However, a loan to one borrower may meet the definition for any or all categories, but a loan does not have to meet all three to be considered a loan to a YBS Farmer.

The following are the current definitions used for YBS farmers:

Young farmer: A farmer, rancher, or producer or harvester of aquatic products who is age 35 or younger as of the loan transaction date.

Beginning farmer: A farmer, rancher, or producer or harvester of aquatic

products who has 10 years or less farming, ranching, or aquatic experience as of the loan transaction date.

Small farmer: A farmer, rancher, or producer or harvester of aquatic products who normally generates less than \$250,000 in annual gross sales of agricultural or aquatic products.

We are seeking comments on the following questions:

Young Farmer

7. Given the trends in the average age of farmers, ranchers, and aquatic operators and the transfer of operations from one generation to the next, does the current age limit remain appropriate? If not, what would be a more meaningful age threshold for a "young" farmer and why?

8. Should the young farmer designation change for a borrower's outstanding loans once they age beyond the threshold?

9. What additional clarification is needed on who qualifies as a young farmer? For example, should the following criteria apply to the determination of whether a person is a young farmer and to what extent:

- Ownership in the agricultural or aquatic operation.
- Ownership of agriculture land only.
- Financial control in the agricultural or aquatic operation.
- Exposure to production risk in the agricultural or aquatic operation.

Beginning Farmer

10. Is the 10-year threshold still appropriate, and if not, what would be an appropriate threshold and why?

11. Should the beginning farmer designation change for a borrower's outstanding loans once the years of experience exceed the threshold?

12. What additional clarification is needed on who qualifies as a beginning farmer? For example, should the following criteria apply to the determination of whether a person is a beginning farmer and to what extent:

- Ownership in the agricultural or aquatic operation.
- Ownership of agriculture land only.
- Financial control in the agricultural or aquatic operation.
- Exposure to production risk in the agricultural or aquatic operation.

Small Farmer

13. What criteria should FCA consider in determining whether to maintain or change the \$250,000 threshold? For example, should we consider thresholds adopted by other government agencies for their definition of "small" farmers?

14. Would it be appropriate to index or benchmark the economic measure

⁹69 FR 16470, March 30, 2004.

used at specified points in the future to ensure the threshold is current and a reasonable measure? If so, what would be an appropriate interval and benchmark?

15. Should the terminology “normally generates” be more clearly defined for reporting purposes? Would a multi-year median or olympic average¹⁰ be a more meaningful measure?

16. Should the measurement for farm or aquatic income reflect a more stable metric compared to the current measure of annual gross sales of agricultural or aquatic products?

17. Should a borrower be considered a small farmer if:

a. They have not yet generated agricultural or aquatic income?

b. They only own agricultural land and no agricultural income is produced?

18. Should there be a time period established over which no agricultural or aquatic income is generated that would disqualify the classification of “small farmer” from continuing?

19. Should the small farmer designation change for a borrower’s outstanding loans if they grow beyond the threshold?

20. Should the small farmer measure account for such items as amount of acreage farmed as well as the production value generated?

Other Reporting Definitions: Material Ownership and Closely Held Entity— Determining whether an entity is a young or beginning farmer.

21. What family connections among individuals who own/operate an entity should be considered to determine whether the entity meets the age or years of experience thresholds?

22. With respect to farming, ranching, and aquatic operations performed through legal entities:

a. What young or beginning farmer ownership thresholds should be used to determine that an operation/entity is a young or beginning farmer?¹¹

b. How should the percentage of ownership in the entity by individuals that meet the requirements for a young or beginning farmer affect the threshold?

c. If a single person’s ownership share is not sufficient to meet the threshold, should more than one person be allowed to jointly meet the threshold?

d. What, if any, overall income threshold should be considered for an entity to be classified as a young or beginning farmer?

¹⁰ Olympic average refers to an average of numbers after removing the highest number and the lowest number.

¹¹ As a reference, section 506(m) of the Federal Crop Insurance Act (7 U.S.C. 1508(m)) sets the minimum beneficial interest level for crop insurance purposes at 5 percent.

23. In determining whether an entity is a young or beginning farmer, over what minimum time period should the Agency provide for an association to make the determination, or should the determination be made at a specific point, for example, at the time the loan is applied for or closed?

In addition to the questions listed above, we are interested in receiving comments on other aspects of the collection and reporting of YBS Farmer data. If providing such information, please designate responses as “Additional Comments”.

Dated: February 12, 2019.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2019-02884 Filed 2-20-19; 8:45 am]

BILLING CODE 6705-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2019-0036; Airspace Docket No. 19-ACE-1]

RIN 2120-AA66

Proposed Amendment of Class E Airspace; Charleston, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface at Charleston, Mississippi County Airport in Charleston, MO. The FAA is proposing this action due to the decommissioning of the Charleston non-directional radio beacon (NDB).

DATES: Comments must be received on or before April 8, 2019.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590, telephone (202) 366-9826, or (800) 647-5527. You must identify FAA Docket No. FAA-2019-0036; Airspace Docket No. 19-ACE-1, at the beginning of your comments. You may also submit comments through the internet at <http://www.regulations.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at http://www.faa.gov/air_traffic/publications/. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11C at NARA, call (202) 741-6030, or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: John Witucki, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222-5900.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would amend Class E airspace at Charleston, Mississippi County Airport, in support of standard instrument approach procedures for IFR operations at the airport.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA-2019-0036; Airspace Docket No. 19-ACE-1." The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at <http://www.regulations.gov>. Recently published rulemaking documents can also be accessed through the FAA's web page at <http://www.faa.gov/air-traffic/publications/airspace-amendments/>.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for the address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending Class E airspace extending upward from 700

feet above the surface within a 6.3-mile radius of Charleston-Mississippi County Airport, Charleston, MO, and removing the extension within 2.6 miles each side of the 190° bearing from the Charleston NDB. This action is necessary due to the decommissioning of the Charleston NDB. This action would enhance safety and the management of IFR operations at the airport.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, would not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

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

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ACE MO E5 Charleston, MO [Amended]

Mississippi County Airport, MO
(Lat. 36°50'32" N, long. 89°21'35" W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Mississippi County Airport.

Issued in Fort Worth, Texas, on February 13, 2019.

John Witucki,

*Acting Manager, Operations Support Group,
ATO Central Service Center.*

[FR Doc. 2019-02840 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-13-P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 230, 232, 239, 240, 270, and 274

[Release Nos. 33-10605; 34-85146; IC-33375; File No. S7-23-18]

RIN 3235-AK60

Reopening of Comment Period for Updated Disclosure Requirements and Summary Prospectus for Variable Annuity and Variable Life Insurance Contracts

AGENCY: Securities and Exchange Commission.

ACTION: Reopening of comment period.

SUMMARY: The Securities and Exchange Commission is reopening the comment period for a proposal to amend rules and forms to help investors make informed investment decisions regarding variable annuity and variable life insurance contracts. The proposal would permit persons to satisfy their prospectus delivery obligations under the Securities Act of 1933 for a variable annuity or variable life insurance contract and any associated portfolio companies by sending or giving a summary contract prospectus to investors and making the statutory and portfolio company prospectuses available online. In addition, the proposal would amend the registration

forms for variable annuity and variable life insurance contracts to update and enhance the disclosures to investors in these contracts, and would require the Inline eXtensible Business Reporting Language (“Inline XBRL”) format for certain required disclosures in the variable contract statutory prospectus. The proposal would also make certain technical and conforming amendments to our rules and forms, as well as rescission of certain related rules and forms, and seek comments regarding parallel amendments to rules governing mutual fund summary prospectuses and registration forms applicable to other types of registered investment companies. The original comment period ended on February 15, 2019. The Commission is reopening the time period in which to provide the Commission with comments until March 15, 2019. This action will allow interested persons additional time to analyze the issues and prepare their comments.

DATES: The comment period for the proposed rule published Nov. 30, 2018 (83 FR 61730), is reopened. Comments should be received on or before March 15, 2019.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment forms (<http://www.sec.gov/rules/proposed.shtml>);
- Send an email to rule-comments@sec.gov. Please include File Number S7–23–18 on the subject line; or
- Use the Federal Rulemaking Portal (<http://www.regulations.gov>). Follow the instructions for submitting comments.

Paper Comments

- Send paper comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to File Number S7–23–18. This file number should be included on the subject line if email is used. To help us process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission’s website (<http://www.sec.gov/rules/proposed.shtml>). Comments also are available for website viewing and printing in the Commission’s Public Reference Room, 100 F Street NE, Room 1580, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. All comments received will be posted without change. 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.

Studies, memoranda or other substantive items may be added by the Commission or staff to the comment file during this rulemaking. A notification of the inclusion in the comment file of any such materials will be made available on the Commission’s website. To ensure direct electronic receipt of such notifications, sign up through the “Stay Connected” option at www.sec.gov to receive notifications by email.

FOR FURTHER INFORMATION CONTACT: Daniel K. Chang, James Maclean, Amy Miller, Senior Counsels; Amanda Hollander Wagner, Branch Chief; Michael C. Pawluk, Senior Special Counsel, Investment Company Regulation Office, at (202) 551–6792; Keith Carpenter or Michael Kosoff, Senior Special Counsels, Disclosure and Review Office, at (202) 551–6921, Division of Investment Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–8549.

SUPPLEMENTARY INFORMATION: The Commission has requested comment on a release proposing new rule 498A [proposed rule 17 CFR 230.498A] under the Securities Act. The release also proposes amendments to the following rules:

Commission reference	CFR citation (17 CFR)
Regulation S-T [17 CFR 232.10 through 232.903]:	
Rule 11	§ 232.11.
Rule 405	§ 232.405.
Securities Act of 1933 (“Securities Act”): ¹	
Rule 159A	§ 230.159A.
Rule 421	§ 230.421.
Rule 431	§ 230.431.
Rule 482	§ 230.482.
Rule 485	§ 230.485.
Rule 497	§ 230.497.
Rule 498	§ 230.498.
Securities Exchange Act of 1934 (“Exchange Act”): ²	
Rule 14a–16	§ 240.14a–16.
Investment Company Act of 1940 (“Investment Company Act”): ³	
Rule 0–1	§ 270.0–1.
Rule 6c–7	§ 270.6c–7.
Rule 6c–8	§ 270.6c–8.
Rule 6e–2	§ 270.6e–2.
Rule 6e–3(T)	§ 270.6e–3(T).
Rule 11a–2	§ 270.11a–2.
Rule 14a–2	§ 270.14a–2.
Rule 26a–1	§ 270.26a–1.
Rule 27c–1	§ 270.27c–1.
Securities Act and Investment Company Act:	
Form N–3	§ 239.17a and 274.11b.
Form N–4	§ 239.17b and 274.11c.
Form N–6	§ 239.17c and 274.11d.

¹ 15 U.S.C. 77a et seq.

² 15 U.S.C. 78a et seq.

³ 15 U.S.C. 80a et seq.

Finally, the release proposes to rescind:

Commission reference	CFR citation (17 CFR)
Investment Company Act:	
Rule 26a-2	§ 270.26a-2.
Rule 27a-1	§ 270.27a-1.
Rule 27a-2	§ 270.27a-2.
Rule 27a-3	§ 270.27a-3.
Rule 27d-2	§ 270.27d-2.
Rule 27e-1	§ 270.27e-1.
Rule 27f-1	§ 270.27f-1.

The Commission originally requested that comments on the release be received by February 15, 2019. The Commission has received several requests for an extension of time for public comment on the proposal to, among other things, allow for adequate time to fully consider the proposals and to improve the quality of responses.⁴ The Commission believes that providing the public additional time to thoroughly consider the matters addressed by the release and to submit comprehensive responses to the release would benefit the Commission in its consideration of final rules.⁵ Therefore, the Commission is reopening the comment period for Release Nos. 33-10569; 34-84508; IC-33286 “Updated Disclosure Requirements and Summary Prospectus for Variable Annuity and Variable Life Insurance Contracts” until March 15, 2019.

By the Commission.

Dated: February 14, 2019.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02906 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1305

[Docket No. DEA-453]

RIN 1117-AB44

New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. DEA published a notice of proposed rulemaking about this new format in November 2007 but did not finalize it. Due to the passage of time and procedural considerations, DEA is reissuing another notice of proposed rulemaking. This proposal supersedes the November 2007 proposal. This proposed rule calls for allowing the continued use of the existing triplicate DEA Form 222 until a sunset date of two years after the final rule becomes effective, which would be included in the final rule. DEA also proposes minor procedural changes, including among other things, to clarify the procedure involving who can issue the power of attorney that is required for others to sign DEA Form 222.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before April 22, 2019. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference “Docket

No. DEA-453” on all correspondence, including any attachments.

Electronic comments: The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions to submit comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on [Regulations.gov](http://www.regulations.gov). If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily

⁴ See Letters from Carl B. Wilkerson, Vice President & Chief Counsel, Securities, American Council of Life Insurers (Dec. 20, 2018), Stephen E. Roth, on behalf of the Committee of Annuity Insurers (Jan. 22, 2019), Benjamin G. Baldwin, Jr. (Feb. 13, 2019). Comments are available on the Commission’s website at <https://www.sec.gov/comments/s7-23-18/s72318.htm>.

⁵ In this regard, the Commission notes that the comment period overlapped in part with the recent lapse in appropriations.

submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place the personal identifying information you do not want to be made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) or confidential business information included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at <http://www.regulations.gov> for easy reference.

Legal Authority and Background

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances (21 U.S.C. 821); maintenance and submission of records and reports (21 U.S.C. 827); and for the efficient execution of his statutory functions (21 U.S.C. 871(b)). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. 21 U.S.C. 958(f). The Attorney General has delegated these authorities to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA previously published a notice of proposed rulemaking (NPRM) on this matter in the **Federal Register** on November 27, 2007 (72 FR 66118). The rulemaking proposed revising the DEA regulations to implement a new format for order forms (DEA Form 222)—issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances—by replacing the three-part carbon-copy form with a single sheet form. During the comment period, DEA received comments from six entities: An organization representing pharmacists, an organization representing pharmaceutical manufacturers and distributors, a pharmaceutical distributor, two reverse distributors, and one individual. Two commenters opposed the proposed rule as written, one supported it with significant concerns, two commenters requested simply the number of line items on the DEA Form 222 be expanded, and one commenter supported the rule and had specific questions regarding distribution of copies for reverse distributors.

The DEA is reissuing another NPRM, superseding the November 2007 NPRM. In this NRPM, the DEA also proposes minor changes to clarify who can issue the power of attorney (POA) that is required for others to sign DEA Form 222.

Order Forms

The CSA requires that schedule I and II controlled substances be only distributed pursuant to a written order made by the purchaser on a form issued by the Attorney General. 21 U.S.C. 828(a). This responsibility has been delegated to the Administrator of DEA (28 CFR 0.100(b)) and redelegated to the Deputy Assistant Administrator of the DEA Diversion Control Division (28 CFR 0.104; section 7(d) of 28 CFR part 0, appendix to subpart R).¹ The DEA uses these order forms to allow tracking of distributions of schedule I and II controlled substances.

Order forms are required for distribution of schedule I and II controlled substances. 21 U.S.C. 828(a); 21 CFR 1305.03. The order forms are issued by DEA to authorized DEA registrants to allow distribution of schedule I and II controlled substances. The order forms are designated as DEA Form 222. The regulations stipulate the forms will be serially numbered and issued with the name, address, and

registration number of the registrant, the authorized activity, and the schedules of the registrant (21 CFR 1305.11(d)). Currently, order forms are three-part carbon forms, printed on interleaved carbon sheets, hereafter also referred to as current or triplicate forms.

Whenever a DEA registrant wishes to acquire a schedule I and/or II controlled substance, that registrant must complete the order form, pursuant to the form instructions, to include the name and address of the supplying DEA registrant, the date requested, the number of packages of controlled substance(s) ordered, the size of the package of the controlled substance(s) ordered, and the name of the controlled substance(s) ordered. Under the current procedures outlined in 21 CFR 1305.13(a), (b), (d), and (e), the purchaser retains one copy (Copy 3) of the triplicate form and sends two copies (Copy 1 and Copy 2) to the supplier so that the order for a controlled substance can be filled. The supplier completes the form by entering the actual number of packages of the controlled substance(s) shipped and the actual date shipped. The supplier retains one copy (Copy 1) of the order form sent to him/her by the purchaser, and sends the other copy (Copy 2) of the order form to the DEA Special Agent in Charge in the area where the supplier is located. Upon receiving the controlled substance(s), the purchaser writes the number of packages of the controlled substance(s) ordered which are actually received and the date received on its copy (Copy 3). Under current 21 CFR 1305.17(a) through (c), both the purchaser and the supplier must preserve their respective copy of the order form for two years and make it available to officials of the DEA for inspection, if requested.

Justification for New Order Form

The proposed new format for DEA Form 222 would employ a single-sheet form, hereafter also referred to as the new form(s). In executing a transaction involving a schedule I and/or II controlled substance, a DEA registrant (purchaser) would process the new single-sheet form in a similar manner to the processing of the current form. The proposed changes in processing include the purchaser retaining a readily retrievable copy, in which copies can be scanned and stored electronically rather than retaining the pre-printed carbon copy. In addition, any registrant supplier who is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) would be required to make

¹ The introductory text of section 7 of 28 CFR part 0, appendix to subpart R allows for the redelegation of responsibility to the Deputy Assistant Administrator of the DEA Office of Diversion Control. However, this office has been reorganized to the DEA Diversion Control Division.

and submit a copy of the original DEA Form 222 to DEA by mail, fax, or email instead of the supplier sending a copy of the original order form. This proposed procedure would replace requiring all suppliers, regardless of ARCOS reporting requirements, to submit Copy 2 to the DEA Special Agent in charge in the area where the supplier is located. The purchaser and supplier would preserve the original order form and a copy of the original order form, respectively, for two years and make it available to officials of the DEA for inspection, if requested. DEA would continue to preprint and issue the new forms.

The single-sheet form would have an issued order form number with enhanced security features over the current form. DEA would preprint the new single-sheet form on security paper to ensure the identity of the original while making it difficult to copy for counterfeit purposes.

The single-sheet form will be more convenient for DEA registrants to utilize. The current format was created more than forty years ago and processing a transaction with carbon copies is outdated. Today, new office technology exists, such as laser printers, scanners and photocopiers, which will allow DEA registrants greater ease in utilizing the single-sheet form.

The single-sheet form will benefit DEA as well. There is only one vendor that produces the current three-part carbon forms which is costly. The Dot Matrix printer used to print the forms is outdated, and DEA can only get replacement parts from one vendor. Maintaining the equipment is costly, difficult, and time-consuming.

Transition From Current to New Order Form

If this regulation is finalized, the new single-sheet form will be used, and DEA would not issue any more triplicate forms. DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition period. When a registrant's supply of triplicate forms is depleted, the DEA would issue the new single-sheet forms. The final rule would include a "sunset date"—a date after which use of the triplicate forms would not be allowed—of two years after the final rule becomes effective. Thus, business firms will have time to shift their processes to accommodate the new single form. For clarity, this rule would revise the existing regulations in part 1305, subpart B to follow the procedures for the issuance and use of the new single-sheet form for the future. The transition procedures allowing the continued use

of existing supplies of the triplicate DEA Form 222 would be relocated to a new § 1305.20.

Revision of DEA Regulations To Accommodate New Order Form

DEA proposes to amend its regulations pertaining to orders for schedule I and II controlled substances, set forth in 21 CFR part 1305, to provide for the use of the single-sheet DEA Form 222. As discussed above, to ease the transition, DEA will allow the continued use of existing stocks of the triplicate forms for a two year transition period.

DEA proposes to amend its regulations to reflect that only one original DEA Form 222 will be provided to authorized registrants by DEA. If finalized, registrants that wish to obtain schedule I and II controlled substances (purchasers) would be required to complete and retain a copy of the form and send the original to their supplier for filling. The supplier would be required to record certain information related to the filling on the original and retain such original. In addition, any supplier who is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) would be required to make and submit a copy of the original DEA Form 222 to DEA by mail (Drug Enforcement Administration, Attn: Registration Section/DRR, P.O. Box 2639, Springfield, VA 22152–2639), fax to (202) 307–5602 or email to DEA.Orderforms@usdoj.gov. The purchaser would be required to record on their copy of the single-sheet form certain information related to the items furnished by the supplier. It is important to note that the process for handling the DEA Forms 222 remains unchanged. The only changes made by these proposed amendments, if finalized, are to require purchasers and suppliers to retain the original of the single-sheet form or to make and retain readily retrievable copies of the form, as applicable, rather than retaining the pre-printed carbon copies. If finalized, the rule also would provide other general procedures related to the single-sheet form (e.g., endorsing forms, cancelling forms, lost or stolen forms, unaccepted or defective forms).

Currently, triplicate forms are issued in mailing envelopes containing seven forms (informally referred to as "books"). The new single-sheet form will not be produced in "books," giving DEA and registrants greater flexibility to request a specific number of order forms. Therefore, in § 1305.11(a), DEA is

proposing to modify the language regarding the new single-sheet DEA Form 222 to indicate that a predetermined number of order forms, based on the business activity of the registrant, will be issued, rather than the current "books" of seven order forms. DEA also proposes to revise § 1305.11(c) to remove language pertaining to "books of DEA Forms 222."

Other Minor Regulatory Changes

The DEA is proposing several minor regulatory changes as part of this rulemaking, as discussed below.

Pursuant to § 1305.05(a), a registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for schedule I and II controlled substances on the registrant's behalf by executing a power of attorney (POA) for each such individual, if the POA is retained in the files, with executed DEA Forms 222 where applicable, for the same period as any order bearing the signature of the POA. The POA must be available for inspection together with other order records.

Under § 1305.05(d), a POA must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the POA is being granted; and two witnesses. DEA proposes to modify this language to increase the accountability to permit other individuals to authorize the POA on behalf of the registrant who is unavailable and is similar to the language found in 21 CFR 1301.13(j) regarding who can sign an application for a DEA registration. For example, if the legal entity that is applying for a DEA registration is a partnership, then either partner may sign the application. If the legal entity that is applying for a DEA registration is a corporation, then any corporate officer may sign the application. DEA is proposing to allow the registrant, if an individual, to execute a POA even though that individual did not sign the last application.

In § 1305.11(b), DEA is proposing to revise the procedure for requisitioning DEA Forms 222 by any person with an active registration that is authorized to order schedule I and II controlled substances to include obtaining them through a secured network connection. As previously discussed, DEA would only be issuing single-sheet forms if the proposed rule were finalized. Due to the advancement of technology, the Diversion Control Division can look at other methods and procedures when single-sheet forms are requested only through a secured network connection

between devices. In § 1305.11(d), DEA is proposing to add procedures for reporting any errors on a DEA Form 222 to the local Division Office.

In § 1305.12(a), DEA is proposing to add a “computer printer” to the list of acceptable methods for filling out a DEA Form 222, in addition to the existing use of a typewriter, pen, or indelible pencil.

Currently, § 1305.13(d) preserves triplicate copies of DEA Form 222 for the supplier. DEA proposes to modify the language to a single-sheet form. A single-sheet Form 222 needs to be available for inspection for a period of two years in accordance with proposed § 1305.17(c).

In § 1305.14(b), DEA is proposing to remove the exception where the name of the supplier is requested on the reporting form, the second supplier must record the name, address, and registration number of the first supplier. DEA has noticed that distribution centers, when reporting to ARCOS, would report themselves as the supplier and not try to record the name, address, and registration number of the first supplier. DEA believes that removing this exception would enable more accurate reporting and recordkeeping.

Regulatory Analysis

DEA conducted a regulatory analysis of the proposed rule to determine how its provisions will impact registrants and the DEA. The results of this analysis are outlined below.

Executive Orders 12866 (Regulatory Planning and Review), 13563, (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563 and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material

way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

1. The DEA expects that this proposed rule will not have an annual effect on the economy of \$100 million or more in at least one year and therefore is not an economically significant regulatory action. DEA’s analysis finds that this proposed rule will result in an annual cost-savings of \$25.9 million; approximately \$22.1 million to purchasers (persons executing DEA Form 222s) primarily due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use; approximately \$0.2 million to non-dispensing suppliers (manufacturers and distributors) due to the elimination of the requirement that registrants mail copies of their completed order forms to their DEA field office; \$2.9 million to dispensing suppliers due to having the option to fax or scan-and-email completed order forms; and \$0.8 million to DEA from reduction in cost of forms production, postage, and equipment maintenance.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. This regulatory action is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

This proposed rule is estimated to have a total cost savings of \$25.9 million. Although this proposed rule is not a significant regulatory action under E.O. 12866, this proposed rule is expected to be an E.O. 13771 deregulatory action.

An economic analysis of the proposed rule can be found in the rulemaking docket at <http://www.regulations.gov>.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator hereby certifies that this proposed rule has been drafted, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it, certifies that this rule will not, if promulgated, have a significant economic impact upon a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. The DEA is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. DEA also proposes minor procedural changes, including among other things, who can issue the power of attorney that is required for others to sign DEA Form 222. This proposed rule affects all parties (purchaser and suppliers) to transactions where a DEA Form 222 is used.

Based on its records, the DEA estimates that 71,481 entities are affected by this rule, which consist of 336 manufacturers, 378 distributors, 31,887 pharmacies, 7,980 hospitals and clinics and 30,900 practitioners. The DEA estimates that 65,984 (92.3%) of

the total 71,481 affected entities are small entities (312 manufacturers, 364 distributors, 31,217 pharmacies, 3,716 hospitals and clinics and 30,375 practitioners). The estimated economic impact varies for purchasers and suppliers, and among the suppliers, dispensing suppliers and non-dispensing suppliers.

“Purchasers” are registrants (primarily pharmacies, practitioners, hospitals and clinics) who execute DEA Form 222 to order Schedules I and II controlled substances. The use of the new single sheet form will require purchasers to make a copy (photocopy or scan) prior to submission to a supplier at an estimated cost of \$0.22 per form, or a total of \$734,646 per year. However, some cost savings are expected due to efficiencies gained from the new form. Key advantages include: (1) Reduction in number of forms executed due to increased number of lines per form, (2) reduction in form failure due to upgraded high-quality secure paper (fewer incidences of tears, carbon not copying through, improper tear of perforated edges, etc.), and (3) increased efficiency in completing the form due to ability to use a computer printer to fill the form (in addition to the existing allowable methods of typewriter, pen, or indelible pencil). Purchasers, as a group, are anticipated to save \$22,794,750, for a net savings of \$22,060,104, or \$312 per entity.

“Dispensing suppliers” are individual or institutional practitioners (e.g., physicians, pharmacies, hospitals, clinics, etc.) that are registered to dispense a controlled substance and may also distribute (without being registered to distribute) a quantity of such substance to another practitioner using a DEA Form 222. The proposed rule would allow the dispensing supplier to submit their copy of the order form to DEA via fax or email, in addition to the currently required submission by mail. Assuming dispensers will opt for the less costly fax or scan-and-email method, based on an estimated 17,480 dispensing suppliers, the DEA estimates the dispensing suppliers, as a group, would save \$2,861,977 per year or \$164 per supplier.

“Non-dispensing suppliers” are persons registered with the DEA as manufacturers or distributors of controlled substances listed in Schedules I or II. The proposed rule and new form would remove the requirement to ship their copies of the received order forms to their DEA field office at the end of each month. The DEA estimates, by removing this requirement, the non-dispensing

suppliers, as a group would save \$239,657 per year, or \$336 per entity.

In summary, the proposed rule is estimated to save Purchasers, Dispensing Suppliers, and Non-Dispensing Suppliers, \$312, \$164, and \$336 per entity per year, respectively. The DEA uses 3% of annual revenue as threshold for “significant economic impact.” The annual revenue at which \$312, \$164, and \$336 is 3% equates to \$10,400, \$5,467, and \$11,200, respectively. The DEA estimates the annual revenues of purchasers, dispensing suppliers, and non-dispensing suppliers are greater than \$10,400, \$5,467, and \$11,200, respectively, resulting in an economic impact of less than 3% of annual revenue.

Therefore, the DEA’s evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), the DEA has identified the following collections of information related to this proposed rule. A person is not required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. Copies of existing information collections approved by OMB may be obtained at <http://www.reginfo.gov/public/do/PRAMain>.

A. Collections of Information Associated With the Notice of Proposed Rulemaking

Title: U.S. Official Order Forms for Schedules I & II Controlled Substances (Accountable Forms), Order Form Requisition.

OMB Control Number: 1117–0010.

Form Number: DEA–222.

The DEA Form 222 provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the

distribution of schedules I and II controlled substances within the closed system of distribution. The DEA is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. Currently, the DEA Form 222 is a triplicate form with interleaved carbon paper.

The new single-sheet format is expected to lower labor burden due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use. Additionally, the proposed rule removes the requirement for Automation of Reports and Consolidated Orders System (ARCOS)-reporting suppliers to mail/ship completed order forms to the DEA field offices. Finally, the proposed rule would also allow non-ARCOS reporting suppliers (generally dispensers who distribute) to submit completed order forms to the respective DEA field offices via fax or email, in addition to mail.

DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition period. When a registrant’s supply of triplicate forms is depleted, the DEA would issue the new single-sheet forms. The final rule would include a “sunset date”—a date after which use of the triplicate forms would not be allowed—of two years after the final rule becomes effective.

This proposed rule does not impact those who use the electronic equivalent order form. The DEA estimates the following number of respondents and burden associated with this collection of information (which includes DEA Form 222 and the electronic equivalent):

- *Number of respondents:* 125,435.
- *Frequency of response:* 59.
- *Number of responses:* 7,400,000 (3,300,000 paper DEA Form 222, 4,100,000 electronic equivalent).
- *Burden per response:* \$0.1392.
- *Total annual hour burden:* 1,030,000.

Due to the elimination for suppliers to mail completed DEA Form 222 to the local DEA field office, the Cost Burden is also eliminated. Due to the provisions of this proposed rule requiring purchasers to make copies of the new single-sheet format for order forms (DEA Form 222), the cost is reduced to \$130,350.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected entities

concerning the proposed collections of information are encouraged. Under the PRA, the DEA is required to provide a notice regarding the proposed collections of information in the **Federal Register** with the Notice of Proposed Rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), the DEA solicits comment on the following issues:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the DEA, including whether the information will have practical utility.

- The accuracy of the DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

- Recommendations to enhance the quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-0010/Docket No. DEA-453. All comments must be submitted to OMB on or before April 22, 2019. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

Congressional Review Act

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

List of Subjects in 21 CFR Part 1305

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set forth above, the DEA proposes to amend 21 CFR part 1305 as follows:

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

■ 2. Amend § 1305.05 by revising paragraph (d) to read as follows:

§ 1305.05 Power of attorney.

* * * * *

(d) A power of attorney must be executed by the registrant, if an individual; by a partner of the registrant, if a partnership; or by an officer of the registrant, if a corporation, corporate division, association, trust or other entity; the person to whom the power of attorney is being granted; and two witnesses.

* * * * *

■ 3. Revise § 1305.11 to read as follows:

§ 1305.11 Procedure for obtaining DEA Forms 222.

(a) DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person with an active registration that is authorized to order schedule I and II controlled substances would be entitled to obtain a DEA Form 222, which will be supplied at any time after the DEA registration is granted. Any person holding a registration authorizing him or her to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting any Division Office or the Registration Section of the Administration through the customer service center.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired. Each requisition must be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute DEA Forms 222 by a power of attorney under § 1305.05.

(d) DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity,

and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local Division Office or the Registration Section of the Administration to modify the registration.

■ 4. Amend § 1305.12 by revising paragraph (a) to read as follows:

§ 1305.12 Procedure for executing DEA Forms 222.

(a) A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil.

* * * * *

■ 5. Amend § 1305.13 by revising paragraphs (a), (b), (d), and (e) to read as follows:

§ 1305.13 Procedure for filling DEA Forms 222.

(a) A purchaser must submit the original DEA Form 222 to the supplier and retain a copy in the purchaser's files.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original and a copy their DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

* * * * *

(d) The supplier must retain the original DEA Form 222 for his or her files in accordance with § 1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) of this chapter (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA by mail (Drug Enforcement Administration, Attn: Registration Section/DRR), fax (202) 307-5602, or email to (DEA.Orderforms@usdoj.gov). The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers

furnished on each item and the dates on which the containers are received by the purchaser.

* * * * *

■ 6. Amend § 1305.14 by revising the first two sentences of paragraph (a) and paragraph (b) to read as follows:

§ 1305.14 Procedure for endorsing DEA Forms 222.

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.13, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided in Part 3 on the original DEA Form 222) the DEA number of the second supplier, and must be signed and dated by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. * * *

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

■ 7. Amend § 1305.15 by revising paragraphs (b) and (d) to read as follows:

§ 1305.15 Unaccepted and defective DEA Forms 222.

* * * * *

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason (e.g. illegible or altered).

* * * * *

(d) When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with § 1305.17. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

■ 8. Amend § 1305.16 by revising paragraphs (a) and (d) to read as follows:

§ 1305.16 Lost and stolen DEA Forms 222.

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, he or she must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received

by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return the original DEA Form 222 to the purchaser, who must attach it to the statement.

* * * * *

(d) If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance.

* * * * *

■ 9. Amend § 1305.17 by revising paragraphs (a), (b), and (c) to read as follows:

§ 1305.17 Preservation of DEA Forms 222.

(a) The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain the original of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

* * * * *

■ 10. Amend § 1305.19 by revising paragraph (a) to read as follows:

§ 1305.19 Cancellation and voiding of DEA Forms 222.

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

* * * * *

■ 11. Add § 1305.20 to read as follows:

§ 1305.20 Transition provisions allowing continued use of existing stocks of triplicate DEA Forms 222.

This section provides the procedures allowing registrants to continue to use existing stocks of the triplicate DEA Form 222, which may continue to be used until [Sunset Date of two years after effective date of final rule]. Registrants are required to use the new single-sheet DEA Form 222 once the

supply of the triplicate forms is exhausted. The provisions of this part are applicable to the use of triplicate forms, except for the specific rules as provided in this section.

(a) *Procedure for obtaining DEA Forms 222.* As set forth in § 1305.11, DEA will no longer issue triplicate forms. Triplicate DEA Forms 222 will not be accepted after [Sunset Date of two years after effective date of final rule].

(b) *Procedure for executing the triplicate DEA Forms 222.* As set forth in § 1305.12:

(1) A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(2) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(3) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(4) Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a DEA Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(5) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

(c) *Procedure for filling triplicate DEA Forms 222.* As set forth in § 1305.13:

(1) A purchaser must submit Copy 1 and Copy 2 of the triplicate DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(2) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and

the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (c)(6) of this section.

(3) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222, except as specified in paragraph (c)(6) of this section.

(4) The supplier must retain Copy 1 of the triplicate DEA Form 222 for his or her files in accordance with paragraph (g)(3) of this section and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(5) The purchaser must record on Copy 3 of the triplicate DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(6) DEA triplicate Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

(d) *Procedure for endorsing triplicate DEA Forms 222.* As set forth in § 1305.14:

(1) A triplicate DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in paragraph (c) of this section, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the triplicate DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. The first supplier may not fill

any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with paragraphs (c)(2) through (4) of this section, including shipping all substances directly to the purchaser.

(2) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

(e) *Unaccepted and defective triplicate DEA Forms 222.* As set forth in § 1305.15:

(1) A DEA Form 222 must not be filled if either of the following apply:

(i) The order is not complete, legible, or properly prepared, executed, or endorsed.

(ii) The order shows any alteration, erasure, or change of any description.

(2) If a triplicate DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g. illegible or altered).

(3) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph (e).

(4) When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with paragraph (g) of this section. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

(f) *Lost and stolen triplicate DEA Forms 222.* As set forth in § 1305.16:

(1) If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, he or she must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. However, if the registrant no longer can use triplicate forms, then the registrant shall

proceed by issuing a new single-sheet form in accordance with § 1305.16.

(2) Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(3) If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(4) If an entire book of triplicate DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(5) If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

(g) *Preservation of triplicate DEA Forms 222.* As set forth in § 1305.17:

(1) The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(2) The supplier must retain Copy 1 of each triplicate DEA Form 222 that it has filled.

(3) Triplicate DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under paragraph (b)(5) of this section), at the registered location printed on the DEA Form 222.

(4) The supplier of thiafentanyl, carfentanyl, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms

222 and records required to be maintained by the registrant.

(h) *Return of unused triplicate DEA Forms 222.* As set forth in § 1305.18, if the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under § 1301.36 of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the nearest office of the Administration.

(i) *Cancellation and voiding of triplicate DEA Forms 222.* As set forth in § 1305.19:

(1) A purchaser may cancel part or all of an order on a triplicate DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

(2) A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (i)(1) of this section.

Dated: February 10, 2019.

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2019-02875 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 10

[Docket No. DOT-OST-2016-0028]

RIN 2105-AE76

Maintenance of and Access to Records Pertaining to Individuals; Correction

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Proposed rule; correction.

SUMMARY: The Department of Transportation is correcting a notice published on February 6, 2019 issue of the **Federal Register** entitled "Maintenance of and Access to Records Pertaining to Individuals". This correction amends the Docket Number of the notice from DOT-OST-2017-0028 to read DOT-OST-2016-0028.

DATES: Effective February 6, 2019.

FOR FURTHER INFORMATION CONTACT: Claire Barrett, Departmental Chief Privacy Officer, Office of the Chief

Information Officer, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590 or privacy@dot.gov or (202) 366-8135.

SUPPLEMENTARY INFORMATION:

Correction

In FR Doc. **Federal Register** at 84-2137 appearing on pages 2137-2138 in the **Federal Register** of Wednesday, February 6, 2019, the following corrections are made:

On page 2137, in the first column in the Title section, "Docket No. DOT-OST-2017-0028 is corrected to read, "Docket No. DOT-OST-2016-0028.

On page 2137, in the first column in the **ADDRESSES** section, "You may file comments identified by the docket number DOT-OST-2017-0028 . . ." is corrected to read, "You may file comments identified by the docket number DOT-OST-2016-0028 . . ."

On page 2137, in the second column in the "Instructions" section, "You must include the agency name and docket number DOT-OST-2017-0028 . . ." is corrected to read, "You must include the agency name and docket number DOT-OST-2016-0028 . . ."

Dated: February 15, 2019.

Claire W. Barrett,

Chief Privacy Officer.

[FR Doc. 2019-02956 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-9X-P

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 15, 2019.

The Department of Agriculture will submit the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13 on or after the date of publication of this notice. Comments are requested regarding: (1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, Washington, DC; New Executive Office Building, 725 17th Street NW, Washington, DC 20503. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@omb.eop.gov or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602.

Comments regarding these information collections are best assured of having their full effect if received by March 25, 2019. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

National Agricultural Statistics Service

Title: Generic Clearance of Survey Improvement Projects.

OMB Control Number: 0535–0248.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue State and national estimates of crop and livestock production, economic and environmental statistics related to agriculture and to conduct the Census of Agriculture under the general authority of Title 7 U.S.C. 2204. The purpose of this generic clearance is to allow NASS to respond quickly to emerging issues and data collection needs. NASS will continue to develop, test, evaluate, adopt, and use state-of-the-art techniques to cover a broad range of topics designed to improve NASS' data collection on agriculture.

Need and Use of the Information: NASS will use a number of survey improvement techniques, as appropriate to the individual project under investigation. These include focus groups, cognitive and usability laboratory and field techniques, exploratory interviews, behavior coding, respondent debriefing, pilot surveys and split-panel tests. The information gathered will be used mainly for questionnaire development and other research and evaluation. Additionally, NASS anticipates the benefit of increased response rates through improved survey design, a goal tied directly to addressing OMB requirements for higher response rates and measurement of non-response bias.

Description of Respondents: Farms.

Number of Respondents: 50,000.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 30,000.

National Agricultural Statistics Service

Title: Quick Response for Cooperative-Funded Surveys Generic Clearance.

OMB Control Number: 0535–NEW.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to prepare and issue State and national estimates of crop and livestock production, economic and environmental statistics related to agriculture and to conduct the Census of Agriculture under the general authority of Title 7 U.S.C. 2204. This generic clearance covers a variety of surveys that will provide valuable statistics to sponsoring cooperators. These data are needed by the cooperators in time frames that make individual clearances impractical.

Need and Use of the Information: NASS would like to conduct up to 15 surveys each year in response to requests from cooperators who have data needs that cannot be met through NASS's annual Congressional appropriations. NASS would like to include surveys that would cover topics such as: Farm management practices, food safety, workplace safety, conservation and land use practices, chemical use management practices, crop quality, agri-tourism, local foods, or other specific agricultural promotion programs.

Description of Respondents: Farms.

Number of Respondents: 75,000.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 37,157.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019–02987 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–20–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

February 15, 2019.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including

the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by March 25, 2019 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW, Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: OIRA_Submission@OMB.EOP.GOV or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Certification of Authority.

OMB Control Number: 0572-0074.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture (USDA). It makes mortgage loans and loan guarantees to finance electric, telecommunications, and water and waste facilities in rural areas. Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.*, as amended, (RE ACT) and as prescribed by Office of Management and Budget (OMB) Circular A-129, Policies for Federal Credit Programs and Non-Tax Receivables, which states that agencies must, based on a review of a loan application, determine that an applicant complies with statutory, regulatory, and administrative eligibility requirements for loan assistance. A major factor in managing loan programs is controlling the advancement of funds. RUS Form 675 allows this control to be achieved by providing a list of authorized signatures against which signatures requesting funds are compared.

Need and Use of the Information: RUS will collect information to ensure that only authorized representatives of the borrower signs the lending requisition form. Without the information RUS would not know if the request for a loan advance was legitimate or not and the potential for waste, loss, unauthorized use, and misappropriation would be increased.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 163.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 16.

Rural Utilities Service

Title: 7 CFR part 1721, Extensions of Payments of Principal and Interest.

OMB Control Number: 0572-0123.

Summary of Collection: The Rural Utilities Service (RUS) electric program provides loans and loan guarantees to borrowers at interest rates and on terms that are more favorable than those generally available from the private sector. Procedures and conditions which borrowers may request extensions of the payment of principal and interest are authorized, as amended, in Section 12 of the Rural Electrification Act of 1936, and Section 236 of the "Disaster Relief Act of 1970 (Pub. L. 91-606), as amended by the Department of Agriculture Reorganization Act of 1994 (Pub. L. 103-354). As a result of obtaining federal financing, RUS borrowers receive economic benefits that exceed any direct economic costs associated with complying with (RUS) regulations and requirements.

Need and Use of the Information: The collection of information occurs only when the borrower requests an extension of principal and interest. Eligible purposes include financial hardship, energy resource conservation loans, renewable energy project, and contributions-in-aid of construction. These procedures are codified at 7 CFR part 1721, subpart B. The collections are made to provide needed benefits to borrowers while also maintaining the integrity of RUS loans and their repayment of taxpayer's monies.

Description of Respondents: Business or other for-profits; Not for-profit institutions.

Number of Respondents: 7.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 61.

Rural Utilities Service

Title: Request for Approval to Sell Capital Assets.

OMB Control Number: 0572-0020.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture (USDA). It makes mortgage loans and loan guarantees to finance electric, telecommunications, and water and waste facilities in rural areas. In addition to providing loans and loan guarantees, one of RUS' main objectives is to safeguard loan security until the loan is repaid. Accordingly, RUS manages loan programs in accordance with the Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.*, as amended, (RE ACT) and as prescribed by Office of Management and Budget (OMB) Circular A-129, Policies for Federal Credit Programs and Non-Tax Receivables, which states that agencies must, based on a review of a loan application, determine that an applicant complies with statutory, regulatory, and administrative eligibility requirements for loan assistance.

Need and Use of the Information: RUS borrower will use form 369, *Request for Approval to Sell Capital Assets*, to seek agency permission to sell some of its assets. The form is used to collect detailed information regarding the proposed sale of a portion of the borrowers systems. RUS will collect information to determine whether or not the agency should approve a sale and also to keep track of what property exists to secure the loan. If the information in Form 369 is not collected when capital assets are sold, the capital assets securing the Government's loans could be liquidated and the Government's security either eliminated entirely or diluted to an undesirable level.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 33.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 99.

Kimble Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2019-02974 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-15-P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS–2018–0106]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of *Phalaenopsis* spp. Plants for Planting in Approved Growing Media From China Into the Continental United States

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of *Phalaenopsis* spp. plants for planting in approved growing media from China into the continental United States.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the *Federal Register*].

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0106>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0106, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0106> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations related to the importation of *Phalaenopsis* spp. plants for planting in approved growing media from China, contact Ms. Lydia Colon, Senior Regulatory Policy Specialist, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1236; (301) 851–2302. For more detailed information on the information

collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of *Phalaenopsis* spp. Plants for Planting in Approved Growing Media From China Into the Continental United States.

OMB Control Number: 0579–0439.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: As authorized by the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture, either independently or in cooperation with States, may carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests that are new to or not widely distributed within the United States.

This authority has been delegated to the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. APHIS regulations contained in “Subpart H—Plants for Planting” (7 CFR 319.37–1 through 319.37–23) prohibit or restrict, among other things, the importation of living plants, plant parts, and seeds for propagation. In accordance with these regulations, plants for planting from certain parts of the world may be imported into the United States only under certain conditions to prevent the introduction of plant pests into the United States.

The importation of *Phalaenopsis* spp. plants for planting from China in approved growing media into the continental United States requires the use of certain information collection activities, including a phytosanitary certificate, written agreement, grower written compliance, inspection, notice of arrival, and emergency action notification.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;
- (2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.49 hours per response.

Respondents: National plant protection organization of China and producers and exporters of *Phalaenopsis* spp. plants for planting in approved growing media from China.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 8.4.

Estimated annual number of responses: 126.

Estimated total annual burden on respondents: 62 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–02849 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service**

[Docket No. APHIS–2018–0105]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Baby Corn and Baby Carrots From Zambia

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the importation of baby corn and baby carrots from Zambia into the continental United States.

DATES: We will consider all comments that we receive on or before April 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0105>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0105, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0105> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the importation of baby corn and baby carrots from Zambia, contact Mr. Juan Roman, Senior Regulatory Policy Specialist, IRM, RCC, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851-2242. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Baby Corn and Baby Carrots From Zambia.

OMB Control Number: 0579-0284.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests into the United States or their dissemination within the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in "Subpart L—Fruits and Vegetables" (7 CFR 319.56-1 through 319.56-12).

In accordance with the regulations, baby corn and baby carrots from Zambia are subject to certain conditions before entering the continental United States to prevent the introduction of plant pests into the United States. The regulations

include requirements for the issuance of a phytosanitary certificate by the national plant protection organization (NPPO) of Zambia stating that the commodity was inspected and found free of the listed pest(s). In addition, there are activities associated with inspection of production sites and emergency action notifications.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

- (2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.13 hours per response.

Respondents: Importers and exporters of baby corn and baby carrots from Zambia and the NPPO of Zambia.

Estimated annual number of respondents: 3.

Estimated annual number of responses per respondent: 5.

Estimated annual number of responses: 15.

Estimated total annual burden on respondents: 17 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, on February 14, 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019-02850 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0084]

Notice of Request for Reinstatement of an Information Collection; Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a reinstatement of an information collection associated with the regulations for import and transport permits.

DATES: We will consider all comments that we receive on or before April 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0084>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0084, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0084> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for import and transport permits, contact Ms. Chelsea Bare, Policy Analyst, Agriculture Select Agent Services, Strategy & Policy, VS, APHIS, 1920 Dayton Ave., Ames, IA 50010; (515) 337-6128. For copies of detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials.

OMB Control Number: 0579–0213.

Type of Request: Reinstatement of an information collection.

Abstract: The Animal Health Protection Act (the Act, 7 U.S.C. 8301 *et seq.*) authorizes the U.S. Department of Agriculture (USDA) to provide for the oversight of the importation, entry, and movement in the United States of animals, pests or diseases, or any material or tangible object that could harbor them. Under the Act, USDA regulates certain organisms, biological agents, toxins, vectors, and animal products that have the potential to pose a severe threat to animal health or to animal products through the risk of disease or pest introduction.

The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within USDA. APHIS regulations for these activities are contained in 9 CFR part 94 (animals or animal products), 9 CFR part 95 (animal byproducts) and 9 CFR part 122 (organisms and vectors). The regulations require an individual or entity, unless specifically exempted under the regulations, to apply for and be granted, by APHIS, a permit authorizing specific import or transport activities for regulated materials prior to engaging in the activities.

APHIS has revised the name of this information collection from “Select Agent Registration” to “Agriculture Select Agent Services; Import and Transport Permits for Non-Select Materials.”

The information collection activities associated with the regulation of select agents and toxins, a related activity, are included in Office of Management and Budget (OMB) control number 0920–0576. In addition to maintaining approval of OMB control number 0920–0576, we are asking OMB to approve our use of these information collection activities, as described, for the non-select agent aspects of the program for 3 years under 0579–0213.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.84 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories, and other interested parties.

Estimated annual number of respondents: 3,214.

Estimated annual number of responses per respondent: 1.

Estimated annual number of responses: 3,283.

Estimated total annual burden on respondents: 6,055 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–02857 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0104]

Notice of Request for an Extension of Approval of an Information Collection; Importation of Citrus From Peru

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service’s intention to request an extension of approval of an information collection associated with importation of citrus from Peru.

DATES: We will consider all comments that we receive on or before April 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0104>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0104, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0104> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on importation of citrus from Peru, contact Mr. Juan Roman, Senior Regulatory Policy Specialist, IRM, RCC, PHP, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737; (301) 851–2242. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS’ Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Citrus From Peru.

OMB Control Number: 0579–0289.

Type of Request: Extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of Agriculture to restrict the importation, entry, or interstate movement of plants, plant products, and other articles to prevent the introduction of plant pests, including fruit flies, into the United States or their dissemination within the United States. Regulations authorized by the PPA concerning the importation of fruits and vegetables into the United States from certain parts of the world are contained in “Subpart L—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–12).

In accordance with the regulations, citrus (grapefruit, limes, mandarins or tangerines, sweet oranges, and tangelos) from Peru is subject to certain conditions before entering the continental United States to prevent the introduction of plant pests into the United States. The regulations require the use of information collection activities, including inspections by national plant protection organization

(NPPO) officials from Peru, grower registration and agreement, fruit fly trapping, monitoring, recordkeeping, and a phytosanitary certificate.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 7.382 hours per response.

Respondents: The NPPO of Peru and importers and growers of citrus fruit from Peru.

Estimated annual number of respondents: 31.

Estimated annual number of responses per respondent: 137.

Estimated annual number of responses: 4,245.

Estimated total annual burden on respondents: 31,339 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, on February 14, 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019-02858 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0107]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Location of Irradiation Treatment Facilities in the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations for the location of irradiation treatment facilities in the United States.

DATES: We will consider all comments that we receive on or before April 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0107>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0107, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0107> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the location of irradiation treatment facilities in the United States, contact Dr. Robert Baca, Assistant Director, Compliance and Environmental Coordination, PPQ, APHIS, 4700 River Road, Unit 150, Riverdale, MD 20737-1231; (301) 851-2292. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

SUPPLEMENTARY INFORMATION:

Title: Location of Irradiation Treatment Facilities in the United States.

OMB Control Number: 0579-0383.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The regulations contained in 7 CFR part 305 (referred to below as the regulations) set out the general requirements for performing treatments and certifying or approving treatment facilities for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture administers these regulations.

Section 305.9 provides generic criteria for new irradiation treatment facilities in the United States to be located anywhere in the United States, subject to approval. APHIS also allows the irradiation treatment of certain imported fruit from various countries upon arrival in the United States. The regulations facilitate the importation of commodities requiring irradiation treatment while continuing to provide protection against the introduction of pests of concern into the United States.

The information collection activities associated with the location of irradiation facilities include request for initial certification and inspection of facility, certification and recertification, denial and withdrawal of certification, compliance agreements, irradiation facilities treating imported articles, irradiation treatment framework equivalency workplan, irradiation facilities notification, recordkeeping, facility contingency plan, letter of concurrence or non-agreement, treatment arrangements, pest management plan, and facility layout map. In addition, each facility must provide APHIS with an updated map identifying places where horticultural or other crops are grown within 4 square miles of the facility.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection: These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 3.13 hours per response.

Respondents: Irradiation facilities in the United States, State governments, importers, and foreign government and national plant protection organization officials.

Estimated annual number of respondents: 19.

Estimated annual number of responses per respondent: 16.6.

Estimated annual number of responses: 315.

Estimated total annual burden on respondents: 987 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

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

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019-02848 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0069]

Availability of an Environmental Assessment for Field Testing of a Vaccine for Use Against Newcastle Disease and Marek's Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an

unlicensed Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector. Based on the environmental assessment, risk analysis, and other relevant data, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment. We are making the documents available to the public for review and comment.

DATES: We will consider all comments that we receive on or before March 25, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0069>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0069, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#/docketDetail;D=APHIS-2018-0069> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information redacted), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100, fax (515) 337-6120.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious before a veterinary biological product license may be issued. Veterinary biological

products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning veterinary biological products are contained in 9 CFR parts 101 to 124.

A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from APHIS, as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS considers the potential effects of this product on the safety of animals, public health, and the environment. Based upon a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Zoetis Inc.

Product: Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

Possible Field Test Locations: Alabama, Arkansas, Delaware, Georgia, Maryland, North Carolina, Pennsylvania, South Carolina, and Virginia.

The above-mentioned product is a live Marek's disease serotype 3 vaccine virus containing a gene from the Newcastle disease virus. It has been shown to be effective for the vaccination of 18 to 19-day-old embryonated chicken eggs or the subcutaneous vaccination of healthy 1-day-old chicks against Marek's disease and Newcastle disease.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA

Implementing Procedures (7 CFR part 372).

We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the associated product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following satisfactory completion of the field test, provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–02854 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2018–0094]

Notice of Request for Reinstatement of an Information Collection; Importation of Swine Hides, Bird Trophies, and Deer Hides

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to

request the reinstatement of an information collection associated with the regulations for the importation of swine hides, bird trophies, and deer hides.

DATES: We will consider all comments that we receive on or before April 22, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0094>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2018–0094, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0094> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of swine hides, bird trophies, and deer hides, contact Dr. Lisa Dixon, Animal Products Import Director, NIES, VS, APHIS, 4700 River Road, Unit 40, Riverdale, MD 20737; (301) 851–3373. For more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Swine Hides, Bird Trophies, and Deer Hides.

OMB Control Number: 0579–0307.

Type of Request: Reinstatement of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States. The regulations are contained in 9 CFR parts 92 through 99.

The regulations in 9 CFR part 95 (referred to below as the regulations) prohibit or restrict the importation of specified animal products into the United States to prevent the introduction of certain contagious animal diseases into the U.S. livestock population. Section 95.16 of the regulations contains, among other things, specific processing, recordkeeping, and certification requirements for untanned hides and skins and bird trophies.

The regulations require that shipments of hides be accompanied by certificates showing their origin and certifying that the hides are from areas free of certain animal diseases. Shipments of ruminant hides from Mexico must be accompanied by written statements indicating that the hides were frozen for 24 hours and treated for ticks. Shipments of bird trophies must be accompanied by certificates of origin certifying that the trophies are from regions free of Newcastle disease and highly pathogenic avian influenza. These activities help ensure that the products do not harbor disease or ticks.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.*, permitting electronic submission of responses.

Estimate of burden: Public burden for this collection of information is estimated to average 0.385 hours per response.

Respondents: National government officials, owners of bird trophies and untanned ruminant and swine hides, and importers of bird trophies and untanned ruminant and swine hides.

Estimated number of respondents: 264.

Estimated number of responses per respondent: 2.8.

Estimated annual number of responses: 738.

Estimated total annual burden on respondents: 284.

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

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019-02856 Filed 2-20-19; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2018-0082]

Availability of an Environmental Assessment for Field Testing of a Vaccine for Use Against Bursal Disease, Marek's Disease, and Newcastle Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector. Based on the environmental assessment, risk analysis, and other relevant data, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment. We are making the documents available to the public for review and comment.

DATES: We will consider all comments that we receive on or before March 25, 2019.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov#!/docketDetail;D=APHIS-2018-0082>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2018-0082, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road, Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket

may be viewed at <http://www.regulations.gov#!/docketDetail;D=APHIS-2018-0082> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737-1231; (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information redacted), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; (515) 337-6100, fax (515) 337-6120.

SUPPLEMENTARY INFORMATION: Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious before a veterinary biological product license may be issued. Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning veterinary biological products are contained in 9 CFR parts 101 to 124.

A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from APHIS, as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS considers the potential effects of this product on the safety of animals, public health, and the environment. Based upon a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Merial, Inc.

Product: Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

Possible Field Test Locations:

Alabama, Arkansas, Georgia, Mississippi, Missouri, North Carolina, Ohio, Oklahoma, Pennsylvania, Tennessee, Texas, and Virginia.

The above-mentioned product is a live Marek's disease serotype 3 vaccine virus containing a gene from the infectious bursal disease virus and a gene from the Newcastle disease virus. It has been shown to be effective for the vaccination of 18 to 19-day-old embryonated chicken eggs or the subcutaneous vaccination of healthy day-old chickens against bursal disease, Marek's disease, and Newcastle disease.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI

to support the issuance of the associated product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following satisfactory completion of the field test, provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 14th day of February 2019.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2019–02855 Filed 2–20–19; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Eastern Region Recreation Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Eastern Region Recreation Resource Advisory Committee (Recreation RAC) will meet in Milwaukee, Wisconsin. The Recreation RAC is established consistent with the Federal Advisory Committee Act of 1972, and the Federal Lands Recreation Enhancement Act. Additional information concerning the Recreation RAC, including details on all fee proposals, can be found by visiting the Recreation RAC's website at: <http://www.fs.usda.gov/main/r9/recreation/racs>.

DATES: The meeting will be held on the following dates:

- Thursday, March 14, 2019, from 1:00 p.m. to 5:00 p.m., and
- Friday, March 15, 2019, from 8:00 a.m. to 12:00 p.m.

All Recreation RAC meetings are subject to cancellation. For updated status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Forest Service—Eastern Regional Office, 626 East Wisconsin Avenue, Milwaukee, Wisconsin. The meeting will be available via teleconference. Visit the Recreation RAC's website at: <http://www.fs.usda.gov/main/r9/recreation/racs> for call-in information.

Written comments may be submitted as described under **SUPPLEMENTARY**

INFORMATION. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Forest Service—Eastern Regional Office. Please call ahead at 541–860–8048 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT:

Joanna Wilson, Eastern Region Recreation RAC Coordinator, by phone at 541–860–8048 or by email at jwilson08@fs.fed.us.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The

purpose of the meeting is to:

(1) Review the following fee proposals:

a. Regional streamline fee proposal by the Recreation Resource Advisory Committee,

b. Monongahela National Forest fee proposals which includes fee increases for Bear Heaven Campground, Laurel Fork Campground, and Red Creek Campground. The proposal also includes a proposed new fee for a daily reservation at Seneca Rocks Picnic Shelter; and

c. Huron Manistee National Forest fee proposal for new fees Red Bridge Access, Sulak Recreation Area, McKinley Horse Trail Campsites, Buttercup Backcountry Campsites, Cathedral Pines Backcountry Group Campsite, Meadow Springs Backcountry Campsites, Bear Island Backcountry Campsites, River Dune Backcountry Campsites, Luzerne Horse Trail Campground, Government Landing Access Campsites, and Upper Manistee River Backcountry Campsites. New group campground fees are proposed for the group sites at AuSable Loop Recreation Area Campground, Mack Lake ORV Campground, Kneff Lake Recreation Area, Gabions Campground, McKinley Horse Trail Campground, Luzerne Horse Trail Campground, and River Road Horse Trail Camp.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by March 1, 2019, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Recreation RAC may file written statements with the Recreation RAC's staff before or after the meeting. Written comments and time requests for oral

comments must be sent to Joanna Wilson, Eastern Region Recreation RAC Coordinator, 221 North 780 East, Salem, Utah 84653; or by email to jwilson08@fs.fed.us.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by case basis.

Dated: February 4, 2019.

Allen Rowley,

Acting Associate Deputy Chief, National Forest System.

[FR Doc. 2019–02981 Filed 2–20–19; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Oklahoma Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Oklahoma Advisory Committee (Committee) will hold a meeting on Tuesday, April 2, 2019 at 2:00 p.m. Central time. The Committee will discuss the implementation stage of their study of the state's 2012 "Civil Rights Initiative," which prohibited preferential treatment or discrimination based on race, color, sex, ethnicity or national origin in public employment, education, and contracting.

DATES: The meeting will take place on Tuesday, April 2, 2019 at 2:00 p.m. Central.

Public Call Information: Dial: 855–719–5012, Conference ID: 1821716.

FOR FURTHER INFORMATION CONTACT: Alejandro Ventura, DFO, at aventura@usccr.gov or (213) 894–3437.

SUPPLEMENTARY INFORMATION: Members of the public may listen to this discussion through the above call in number. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with

(if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1-800-877-8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Regional Programs Unit, U.S. Commission on Civil Rights, 230 S Dearborn, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353-8324, or emailed to Corrine Sanders at csanders@usccr.gov. Persons who desire additional information may contact the Regional Programs Unit at (312) 353-8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via www.facadatabase.gov under the Commission on Civil Rights, Oklahoma Advisory Committee link. 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.

Dated: February 15, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019-02920 Filed 2-20-19; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Vermont Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of briefing 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 community forum of the Vermont Advisory Committee to the Commission will convene at 3:00 p.m.

(EST) on Monday, March 4, 2019, in the Community Room at the Brattleboro Savings and Loan located at 221 Main Street, in Brattleboro, VT 05301. The purpose of the community forum is to hear from advocates and community members about school discipline and civil rights in Vermont public schools.

DATES: Monday, March 4, 2019 (EST).

TIMES: 5:30 p.m. to 8:00 p.m.

ADDRESSES: Community Room, Brattleboro Savings and Loan, 221 Main Street, Brattleboro, VT 05301.

FOR FURTHER INFORMATION CONTACT:

Evelyn Bohor at ebohor@usccr.gov, or 202-376-7533.

SUPPLEMENTARY INFORMATION: If other persons who plan to attend the meeting require other accommodations, please contact Evelyn Bohor at ebohor@usccr.gov at the Eastern Regional Office at least ten (10) working days before the scheduled date of the meeting.

Time will be set aside at the end of the briefing so that members of the public may address the Committee after the formal presentations have been completed. Persons interested in the issue are also invited to submit written comments; the comments must be received in the regional office by Thursday, April 4, 2019. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376-7548, or emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376-7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at <https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzmXAAQ>, and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, www.usccr.gov, or to contact the Eastern Regional Office at the above phone number, email or street address.

Tentative Agenda

Monday, March 4, 2019 at 3:00 p.m.

- I. Welcome and Introductions
- II. Community Form
- IV. Adjournment

Dated: February 15, 2019.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2019-02919 Filed 2-20-19; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; 2019 National Survey of Psychiatrists

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the proposed 2019 National Survey of Psychiatrists, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before April 22, 2019.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW, Washington, DC 20230 (or via the internet at PRAcomments@doc.gov). You may also submit comments, identified by Docket Number USBC-2018-0018 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.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Elizabeth Sinclair, U.S. Census Bureau, ADDP, HQ-7H036F, 4600 Silver Hill Road, Washington, DC 20233-0001, (301)-763-3748 (or via the internet at Elizabeth.Sinclair@census.gov).

SUPPLEMENTARY INFORMATION:**I. Abstract**

Sponsored by the U.S. Department of Health and Human Services' (HHS') Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT), the National Survey of Psychiatrists (NSP) is conducted to assist in fulfilling the Congressional mandates of Programmatic Authority 42 U.S.C. 290aa.

The NSP is designed to obtain the necessary data to determine the characteristics and distribution of psychiatrists throughout the United States, as well as emerging patterns in their employment characteristics. These data will provide the means for the evaluation and assessment of the evolving demographics, career employment patterns, and populations served, consistent with the goals of congressional mandates of the 42 U.S.C. 290aa. Such data have become particularly important for the need to better understand psychiatry workforce demands given the recent transformation of the healthcare system.

The proposed survey design for the 2019 NSP will include a probability sample (not to exceed 30,000 psychiatrists) selected from a sampling frame compiled from files provided by the American Medical Association (AMA) and American Osteopathic Association (AOA). These files constitute a universe frame of all physicians licensed in the 50 States and the District of Columbia. The Census Bureau is acquiring a segment of the files, that contain the flagged psychiatrists records. Sampling rates are set based on considerations of statistical precision of the estimates and the costs involved in obtaining reliable estimates. The survey will be multi-mode offering respondents the opportunity to participate via a web instrument and a paper questionnaire.

The 2019 NSP project includes plans to experimentally test the efficacy of a non-monetary incentive (that is, whether offering a non-monetary incentive as a token of appreciation increases response, thus reducing non-response bias and reducing costs associated with follow-up). A pressure-sealed reminder postcard is scheduled to be mailed approximately one week after the initial survey invite mailing. This strategy is being implemented to decrease the time gap during mailings and is more cost-effective than sending a paper questionnaire packet. The ability to send reminders enclosed with the pressure-seal system allows for the secure delivery of login information for

the NSP web instrument as well as specific information about the survey. Additionally, the project will test contact materials, and test modifications to data collection strategies based on response from prior contact strategies.

In addition to testing non-monetary incentives, the 2019 NSP will evaluate different non-response follow-up mailing strategies by testing for response improvements using targeted paper questionnaires in mailing #3. Providing a respondent with an alternate, potential preferred mode sooner will be evaluated.

Third, we plan to experimentally evaluate the impact of adding SAMHSA letterhead to the contact materials for mailing #5. The Substance Abuse and Mental Health Services Administration is well known among the psychiatrists population. The familiarity for this relationship may impact a respondent's likelihood to participate.

Finally, for respondents who experience technical problems with the web instrument, have questions about the survey, or need other forms of assistance, the 2019 NSP will have a Telephone Questionnaire Assistance (TQA) line available. TQA staff will not only be able to answer respondent questions and concerns, but also they will have the ability to collect survey responses over the phone. Respondents can call in and via an administrative access to the web instrument have interviewer assistance in completing the survey.

II. Methods of Collection*Web-Push*

The 2019 NSP production plan is a web-push data collection design. All sample psychiatrists receive an initial invite to respond to the survey with instructions on how to complete the questionnaire via the web. The web-push production is broken out into two non-monetary incentive groups: The majority (80% of sampled psychiatrists), will receive a non-monetary incentive; a small group (20% of sampled psychiatrists), will not receive a non-monetary incentive, which allows the effectiveness of the non-monetary incentive to be evaluated. No additional incentives are planned for subsequent follow-up reminders or paper questionnaire mailings.

Mixed-Mode

The follow-up non-response mailings will include target paper mailings and eventually all non-response sample psychiatrists will receive a paper questionnaire.

III. Data

OMB Control Number: 0607-XXXX.

Form Number: NSP.

Type of Review: Regular submission.

Affected Public: Psychiatrists, researchers, and policymakers.

Estimated Number of Respondents: 12,000.

Estimated Time per Response: 20 minutes per response.

Estimated Total Annual Burden Hours: 4,000 hours.

Estimated Total Annual Cost to Public: \$0 (This is not the cost of respondents' time, but the indirect costs respondents may incur for such things as purchases of specialized software or hardware needed to report, or expenditures for accounting or records maintenance services required specifically by the collection.)

Respondent's Obligation: Voluntary.

Legal Authority:

Census Authority: 13 U.S.C. 8(b).

SAMSHA Authority: 42 U.S.C. 290aa.

Confidentiality: The data collected under this agreement are confidential under 13 U.S.C. 9. All access to Title 13 data from this survey is restricted to those holding Census Bureau Special Sworn Status pursuant to 13 U.S.C. 23(c).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019-02943 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE**Bureau of Economic Analysis****American Workforce Policy Advisory Board**

AGENCY: Bureau of Economic Analysis, Office of the Under Secretary for Economic Affairs, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Under Secretary for Economic Affairs announces the March 6, 2019 inaugural meeting of the American Workforce Policy Advisory Board (Workforce Advisory Board). The Advisory Board advises the National Council for the American Worker (National Council) on how the Federal Government can encourage the private sector and educational institutions to combat the skills crisis by investing in and increasing demand-driven education, training, and re-training for American workers. The discussions for this inaugural meeting include a review of the National Council's priority areas and identification of areas of activity for the Workforce Advisory Board.

DATES: The Workforce Advisory Board will meet on March 6, 2019; the meeting will begin at 2 p.m. and end at approximately 5 p.m. (EST).

ADDRESSES: The meeting will be in the Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20502. The meeting is open to the public via audio conference technology. Audio instructions will be prominently posted on the Workforce Advisory Board homepage at: <https://www.commerce.gov/americanworker/american-workforce-policy-advisory-board>. Please note: The Workforce Advisory Board website will maintain the most current information on the meeting agenda, schedule, and location. These items may be updated without further notice in the **Federal Register**.

The public may also submit statements or questions via the Advisory Board email address, AmericanWorkforcePolicyAdvisoryBoard@doc.gov (please use the subject line "March 2019 Advisory Board Meeting Public Comment"), or by letter to Ken White, Office of Under Secretary for Economic Affairs, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. If you wish the Workforce Advisory Board to consider your statement or question during the meeting, we must receive your written statement or question no later than 5 p.m. (EST) two business days prior to the meeting. We will provide all statements or questions

received after the deadline to the members, however they may not consider them during the meeting.

FOR FURTHER INFORMATION CONTACT: Ken White, Office of Under Secretary for Economic Affairs, Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, (202) 482-2406, or white2@doc.gov.

SUPPLEMENTARY INFORMATION: In Executive Order 13845 (July 19, 2018), as amended, the President charged the National Council to develop a national strategy to ensure that America's students and workers have access to affordable, relevant, and innovative education and job training that will equip them to compete and win in the global economy and to monitor the implementation of that strategy. In the same Executive Order, the President created the Workforce Advisory Board to advise the National Council in its efforts to work with private employers, educational institutions, labor unions, other non-profit organizations, and State, territorial, tribal, and local governments to update and reshape America's education and job training landscape so that it better meets the needs of American students, workers, and businesses. The Workforce Advisory Board shall be co-chaired by the Secretary of Commerce and the Advisor to the President overseeing the Office of Economic Initiatives. In addition to the co-chairs, the Workforce Advisory Board comprises as many as 25 members appointed by the Secretary of Commerce. Members include individuals chosen to serve as representatives of the various sectors of the economy, including the private sector, employers, educational institutions, and States to offer diverse perspectives on how the federal government can improve education, training, and re-training for American workers.

In an advisory capacity, the Workforce Advisory Board supports the National Council in any of its functions, including:

- Building national campaigns to raise awareness of matters such as the urgency of the skills crisis, the creation of new industries and job opportunities through emerging technologies, the importance of manufacturing and trade careers, and the need for corporate training investments;
- Increasing transparency related to education and job-training program options, including those offered at 4-year institutions and community colleges;
- Proposing ways to increase access to job-related data (*i.e.*, data on

industries, geographic locations, open jobs, projected future opportunities, and the underlying required skills) and fostering close coordination within the federal government and between the government and non-federal stakeholders;

- Developing recommendations on how the public sector should engage with the private sector in worker re-training, including through the use of online learning resources;
- Examining public and private-sector expenditures, including tax expenditures, on worker education and training; and
- Recognizing companies that demonstrate excellence in workplace education, training, and re-training policies.

Dated: February 15, 2019.

Jeremy Pelter,

Chief Financial Officer, Bureau of Economic Analysis.

[FR Doc. 2019-03044 Filed 2-19-19; 11:15 am]

BILLING CODE

DEPARTMENT OF COMMERCE**Foreign-Trade Zones Board**

[B-58-2018]

Foreign-Trade Zone (FTZ) 44—Trenton, New Jersey; Authorization of Production Activity; International Flavors & Fragrances, Inc. (Flavor and Fragrance Products), Hazlet, New Jersey

On September 6, 2018, International Flavors & Fragrances, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 44B, in Hazlet, New Jersey.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (83 FR 47328, September 19, 2018). On February 13, 2019, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: February 14, 2019.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2019-02983 Filed 2-20-19; 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: Preliminary Results of Antidumping Duty Administrative Review; 2016-2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sales of circular welded carbon-quality steel pipe (CWP) from the United Arab Emirates (UAE) have been made below normal value. We invite interested parties to comment on these preliminary results.

DATES: Applicable February 21, 2019.

FOR FURTHER INFORMATION CONTACT: Manuel Rey or 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) 482-5518 or (202) 482-6274, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on CWP from the UAE. The notice of initiation of this administrative review was published on February 23, 2018.¹ This review covers nine producers and exporters of the subject merchandise. The period of review is June 8, 2016 through November 30, 2017. Commerce exercised its discretion to toll all deadlines affected by the partial federal government closure from December 22,

2018, through the resumption of operations on January 29, 2019.² If the new deadline falls on a non-business day, in accordance with Commerce's practice, the deadline will become the next business day. The revised deadline for the preliminary results is now February 12, 2019.

Commerce selected two mandatory respondents for individual examination: Ajmal Steel Tubes & Pipes Ind. L.L.C. (Ajmal)/Noble Steel Industries L.L.C (Noble Steel) (collectively, Ajmal Steel)³ and Universal Tube and Plastic Industries, Ltd./THL Tube and Pipe Industries LLC (TTP)/KHK Scaffolding and Formwork LLC (collectively, Universal).⁴ In August 2018, Commerce extended the preliminary results of this review to no later than January 3, 2019.⁵

Scope of the Order

The merchandise subject to the order is welded carbon-quality steel pipes and tube, of circular cross-section, with an outside diameter not more than nominal 16 inches (406.4 mm), regardless of wall thickness, surface finish (e.g., black, galvanized or painted), end finish (plain end, beveled end, grooved, threaded, or threaded and coupled), or industry specification (e.g., American Society for Testing and Materials International (ASTM), proprietary, or other), generally known as standard pipe, fence pipe and tube, sprinkler pipe, and structural pipe (although subject product may also be referred to as mechanical tubing). The products subject to this order are currently classifiable in Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting numbers 7306.19.1010, 7306.19.1050, 7306.19.5110, 7306.19.5150, 7306.30.1000, 7306.30.5015, 7306.30.5020, 7306.30.5025, 7306.30.5032, 7306.30.5040, 7306.30.5055, 7306.30.5085,

7306.30.5090, 7306.50.1000, 7306.50.5030, 7306.50.5050, and 7306.50.5070. Although the HTSUS numbers are provided for convenience and for customs purposes, the written product description remains dispositive.⁶

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) and (2) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, see the Preliminary Decision Memorandum. The Preliminary 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 to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and electronic versions of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of the Review

As a result of this review, we preliminarily determine that weighted-average dumping margins exist for the respondents for the period June 8, 2016, through November 30, 2017, as follows:

Exporter/producer	Weighted-average dumping margin (percent)
Ajmal Steel Tubes & Pipe Ind. L.L.C./Noble Steel Industries L.L.C	5.28

¹ See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 83 FR 8058 (February 23, 2018) (*Initiation Notice*).

² See Memorandum, "Deadlines Affected by the Partial Shutdown of the Federal Government," dated January 28, 2019. All deadlines in this segment of the proceeding have been extended by 40 days.

³ On December 11, 2018, we preliminarily collapsed Ajmal and Noble Steel. See Memorandum, "Whether to Collapse Ajmal Steel Tubes and Pipes Ind. L.L.C. and Noble Steel Industries L.L.C. in the 2016-2017 Antidumping

Duty Administrative Review of Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates," dated December 11, 2018.

⁴ On January 31, 2019, we preliminarily found that TTP is the successor-in-interest to Universal Tube and Pipe Industries Limited. See Memorandum, "Successor-In-Interest Determination in the 2016-2017 Antidumping Duty Administrative Review on Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates," dated January 31, 2019.

⁵ See Memorandum, "Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates:

Extension of the Deadline for Preliminary Results of Antidumping Duty Administrative Review," dated August 23, 2018.

⁶ For a complete description of the scope of the Order, see Memorandum, "Decision Memorandum for the Preliminary Results of the 2016-2017 Administrative Review of the Antidumping Duty Order on Circular Welded Carbon-Quality Steel Pipe from the United Arab Emirates," dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Exporter/producer	Weighted-average dumping margin (percent)
Universal Tube and Plastic Industries, Ltd./Universal Tube and Pipe Industries Limited/THL Tube and Pipe Industries LLC ^{7/} KHK Scaffolding and Formwork LLC	1.65

Review-Specific Average Rate
Applicable to the Following
Companies:⁸

Exporter/producer	Weighted-average dumping margin (percent)
Abu Dhabi Metal Pipes and Profiles Industries Complex	3.47
Ferrolab LLC	3.47
Global Steel Industries	3.47
Lamprell	3.47
Link Middle East Ltd	3.47
PSL FZE	3.47
Three Star Metal Ind LLC	3.47

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.⁹ Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.¹⁰ Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.¹¹ Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.¹² Case and rebuttal briefs should be filed using ACCESS.¹³

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.¹⁴ Hearing requests should contain: (1) The party's name, address, and telephone

number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.¹⁵

Commerce intends to issue the final results of this administrative review, including the results of its analysis raised in any written briefs, not later than 120 days after the publication date of this notice, pursuant to section 751(a)(3)(A) of the Act, unless otherwise extended.¹⁶

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries.

Pursuant to 19 CFR 351.212(b)(1), because Ajmal Steel and Universal reported the entered value of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined

sales to the total entered value of the sales for which entered value was reported. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. We intend to instruct CBP to take into account the "provisional measures deposit cap," in accordance with 19 CFR 351.212(d).

For the companies which were not selected for individual review, we will assign an assessment rate based on the average¹⁷ of the cash deposit rates calculated for Ajmal Steel and Universal, excluding any which are *de minimis* or determined entirely based on adverse facts available. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

Commerce's "automatic assessment" practice will apply to entries of subject merchandise during the POR produced by companies included in these final results of review for which the reviewed

⁷ As noted above, we preliminarily determined that THL Tube and Pipe Industries LLC is the successor-in-interest to Universal Tube and Pipe Industries Limited.

⁸ This rate is based on the simple average margin using the publicly-ranged data calculated for those companies selected for individual review. Because we cannot apply our normal methodology of calculating a weighted-average margin due to requests to protect business proprietary

information, we find this rate to be the best proxy of the actual weighted-average margin determined for the mandatory respondents. See *Ball Bearings and Parts Thereof from France, et al.: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part*, 75 FR 53661, 53663 (September 1, 2010).

⁹ See 19 CFR 351.224(b).

¹⁰ See 19 CFR 351.309(c).

¹¹ See 19 CFR 351.309(d).

¹² See 19 CFR 351.309(c)(2) and (d)(2).

¹³ See 19 CFR 351.303.

¹⁴ See 19 CFR 351.310(c).

¹⁵ See 19 CFR 351.310(d).

¹⁶ See section 751(a)(3)(A) of the Act.

¹⁷ This rate was calculated as discussed in footnote 7, above.

companies did not know that the merchandise they sold to the intermediary (e.g., a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.¹⁸

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the exporters listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) if the exporter is not a firm covered in this review, or the original less-than-fair-value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (3) the cash deposit rate for all other manufacturers or exporters will continue to be 5.95 percent, the all-others rate made effective by the LTFV investigation.¹⁹ These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the

subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: February 8, 2019.

Christian Marsh,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Order
- IV. Affiliation and Collapsing
- V. Successor-in-Interest
- VI. Companies Not Selected for Individual Examination
- VII. Discussion of the Methodology
 - A. Date of Sale
 - B. Normal Value Comparisons
 - C. Determination of Comparison Method
 - D. Product Comparisons
 - E. Export Price/Constructed Export Price
 - F. Normal Value
 - i. Home Market Viability and Comparison Market
 - ii. Level of Trade
 - iii. Affiliated-Party Transactions and Arm's-Length Test
 - iv. Cost of Production (COP) Analysis
 1. Cost Averaging Methodology
 - a. Significant of Cost Changes
 - b. Linkage Between Sales and Cost Information
 2. Calculation of COP
 3. Test of Comparison Market Sales Prices
 4. Results of the COP Test
 - v. Calculation of Normal Value Based on Comparison Market Prices
- VIII. Currency Conversion
- IX. Recommendation

[FR Doc. 2019-02984 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advisory Committee on Earthquake Hazards Reduction Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: National Institute of Standards and Technology (NIST)'s Advisory Committee on Earthquake Hazards Reduction (ACEHR or Committee) will hold an open meeting via webinar on March 12, 2019, from 3:00 p.m. to 5:00 p.m. Eastern Time.

DATES: The ACEHR will meet via webinar on Tuesday, March 12, 2019,

from 3:00 p.m. to 5:00 p.m. Eastern Time.

ADDRESSES: The meeting will be held via webinar. Please note participation instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tina Faecke, Management and Program Analyst, National Earthquake Hazards Reduction Program (NEHRP), Engineering Laboratory, NIST, 100 Bureau Drive, Mail Stop 8604, Gaithersburg, Maryland 20899-8604. Ms. Faecke's email address is tina.faecke@nist.gov and her phone number is (301) 975-5911.

SUPPLEMENTARY INFORMATION:

Authority: Section 103 of the NEHRP Reauthorization Act of 2004 (Pub. L. 108-360), 42 U.S.C. 7704, and the Federal Advisory Committee Act, as amended, 5 U.S.C. App. The Committee is composed of 11 members, appointed by the Director of NIST, who were selected for their established records of distinguished service in their professional community, their knowledge of issues affecting NEHRP, and to reflect the wide diversity of technical disciplines, competencies, and communities involved in earthquake hazards reduction. In addition, the Chairperson of the U.S. Geological Survey Scientific Earthquake Studies Advisory Committee serves as an ex-officio member of the Committee.

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the ACEHR will meet via webinar on Tuesday, March 12, 2019, from 3:00 p.m. to 5:00 p.m. Eastern Time. The meeting will be open to the public. The primary purpose of this meeting is for the Committee to develop a draft of their 2019 biennial Report on the Effectiveness of the NEHRP. The agenda may change to accommodate Committee business. The final agenda and any meeting materials will be posted on the NEHRP website at <http://nehrrp.gov/>.

Individuals and representatives of organizations who would like to offer comments and suggestions related to the Committee's business are invited to request a place on the agenda. Approximately fifteen minutes will be reserved from 4:45 p.m.-5:00 p.m. Eastern Time for public comments and speaking times will be assigned on a first-come, first-serve basis. The amount of time per speaker will be determined by the number of requests received but is likely to be about three minutes each. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Tina

¹⁸ For a full discussion of this practice, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

¹⁹ See *Circular Welded Carbon-Quality Steel Pipe from the Sultanate of Oman, Pakistan, and the United Arab Emirates: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Orders*, 81 FR 91906 (December 19, 2016).

Faecke, tina.faecke@nist.gov by 5:00 p.m. Eastern Time, Wednesday, March 6, 2019. Speakers who wish to expand upon their oral statements, those who had wished to speak but could not be accommodated on the agenda, and those who were unable to participate are invited to submit written statements to ACEHR, National Institute of Standards and Technology, Mail Stop 8604, 100 Bureau Drive, Gaithersburg, MD 20899, via fax at (301) 975-4032, or electronically by email to tina.faecke@nist.gov.

All participants in the meeting are required to pre-register. Anyone wishing to participate must register by 5:00 p.m. Eastern Time, Wednesday, March 6, 2019. Please submit your first and last name, email address, and phone number to Tina Faecke at tina.faecke@nist.gov or (301) 975-5911. After pre-registering, participants will be provided with detailed instructions on how to join the webinar.

Kevin A. Kimball,
Chief of Staff.

[FR Doc. 2019-02978 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No.: 190204061-9061-01]

National Cybersecurity Center of Excellence (NCCoE) Critical Cybersecurity Hygiene: Patching the Enterprise Building Block

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice.

SUMMARY: The National Institute of Standards and Technology (NIST) invites organizations to provide products and technical expertise to support and demonstrate security platforms for the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block. This notice is the initial step for the National Cybersecurity Center of Excellence (NCCoE) in collaborating with technology companies to address cybersecurity challenges identified under the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block. Participation in the building block is open to all interested organizations.

DATES: Collaborative activities will commence as soon as enough completed and signed letters of interest have been returned to address all the necessary

components and capabilities, but no earlier than March 25, 2019.

ADDRESSES: The NCCoE is located at 9700 Great Seneca Highway, Rockville, MD 20850. Letters of interest must be submitted to cyberhygiene@nist.gov or via hardcopy to National Institute of Standards and Technology, NCCoE; 9700 Great Seneca Highway, Rockville, MD 20850. Organizations whose letters of interest are accepted in accordance with the process set forth in the **SUPPLEMENTARY INFORMATION** section of this notice will be asked to sign a consortium Cooperative Research and Development Agreement (CRADA) with NIST. An NCCoE consortium CRADA template can be found at: <https://www.nccoe.nist.gov/sites/default/files/library/nccoe-consortium-crada-example.pdf>.

FOR FURTHER INFORMATION CONTACT:

Alper Kerman and Murugiah Souppaya via email to cyberhygiene@nist.gov; by telephone 301-975-0226 and 301-975-8443; or by mail to National Institute of Standards and Technology, NCCoE; 9700 Great Seneca Highway, Rockville, MD 20850. Additional details about the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block are available at <https://www.nccoe.nist.gov/sites/default/files/library/project-descriptions/ch-pe-project-description-draft.pdf>.

SUPPLEMENTARY INFORMATION: Interested parties must contact NIST to request a letter of interest template to be completed and submitted to NIST. Letters of interest will be accepted on a first come, first served basis. When the building block has been completed, NIST will post a notice on the NCCoE Critical Cybersecurity Hygiene: Patching the Enterprise Building Block website at <https://www.nccoe.nist.gov/sites/default/files/library/project-descriptions/ch-pe-project-description-draft.pdf> announcing the completion of the building block and informing the public that it will no longer accept letters of interest for this building block.

Background: The NCCoE, part of NIST, is a public-private collaboration for accelerating the widespread adoption of integrated cybersecurity tools and technologies. The NCCoE brings together experts from industry, government, and academia under one roof to develop practical, interoperable cybersecurity approaches that address the real-world needs of complex Information Technology (IT) systems. By accelerating dissemination and use of these integrated tools and technologies for protecting IT assets, the NCCoE will enhance trust in U.S. IT communications, data, and storage

systems; reduce risk for companies and individuals using IT systems; and encourage development of innovative, job-creating cybersecurity products and services.

Process: NIST is soliciting responses from all sources of relevant security capabilities (see below) to enter into a Cooperative Research and Development Agreement (CRADA) to provide products and technical expertise to support and demonstrate security platforms for the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block. The full building block can be viewed at: <https://www.nccoe.nist.gov/sites/default/files/library/project-descriptions/ch-pe-project-description-draft.pdf>.

Interested parties should contact NIST using the information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. NIST will then provide each interested party with a letter of interest template, which the party must complete, certify that it is accurate, and submit to NIST. NIST will contact interested parties if there are questions regarding the responsiveness of the letters of interest to the building block objective or requirements identified below. NIST will select participants who have submitted complete letters of interest on a first come, first served basis within each category of product components or capabilities listed below up to the number of participants in each category necessary to carry out this building block. However, there may be continuing opportunity to participate even after initial activity commences. Selected participants will be required to enter into a consortium CRADA with NIST (for reference, see **ADDRESSES** section above). NIST published a notice in the **Federal Register** on October 19, 2012 (77 FR 64314) inviting U.S. companies to enter into National Cybersecurity Excellence Partnerships (NCEPs) in furtherance of the NCCoE. For this demonstration project, NCEP partners will not be given priority for participation.

Building Block Objective: The objective of this building block is to demonstrate a proposed approach for improving enterprise patching practices for general IT systems. A detailed description of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block is available at: <https://www.nccoe.nist.gov/sites/default/files/library/project-descriptions/ch-pe-project-description-draft.pdf>.

Requirements: Each responding organization's letter of interest should identify which security platform component(s) or capability(ies) it is

offering. Letters of interest should not include company proprietary information, and all components and capabilities must be commercially available. Components are listed in section 3 of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block (for reference, please see the link in the PROCESS section above) and include, but are not limited to:

- Personal computers (PCs) and mobile devices, including operating systems, firmware, and apps
- Unified endpoint management (UEM), enterprise mobility management (EMM), mobile device management (MDM), and mobile application management (MAM) solutions
- Firewalls and intrusion detection/protection systems
- Routers/switches
- Network-based storage
- Update sources
- Privilege access management (PAM) system and privileged access workstation
- Configuration management system
- Vulnerability management system
- On-premises datacenter and cloud infrastructure, including servers, virtual machine (VM) hosts, VMs, containers, apps, and firmware

Each responding organization's letter of interest should identify how their products address one or more of the following desired solution characteristics in section 2 of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block (for reference, please see the link in the PROCESS section above):

1. Free or commercial tools will be harnessed to enable inventory capabilities so that the assets in the form of firmware, operating systems, and applications across the environment can be discovered, identified, classified for different impact levels and then prioritized for the order of remediation.

2. Patches will be deployed on scheduled intervals as part of regular release cycles, as well as on demand upon active patching emergencies in crisis situations to endpoint firmware, OS, and applications hosted on-premises or in the cloud (*e.g.*, Infrastructure as a Service), as well as "network devices" like firewalls, Storage Area Network (SAN) devices, routers, network switches, and other network appliances.

3. A cloud delivery model will be used as the mechanism for patching, such as a mobile device or a "Windows as a Service (WaaS)" model with Windows operating systems, Apple Software Update, and mobile software updates for Android and iOS devices

provided by device manufacturers or mobile operators.

4. Vulnerabilities will be identified and categorized across the assets so that the appropriate patches can be deployed in a prioritized order for optimum effectiveness.

5. There will be implementation procedures for isolation methods in place for assets that cannot be easily patched such as legacy unsupported systems or systems with very high operational availability requirements.

6. There will be stringent security practices in place to safeguard the patch management systems and any associated components used to support the patch management activities.

Responding organizations need to understand and, in their letters of interest, commit to provide:

1. Access for all participants' project teams to component interfaces and the organization's experts necessary to make functional connections among security platform components.

2. Support for development and demonstration of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block in NCCoE facilities which will be conducted in a manner consistent with the following standards and guidance: FIPS 200, FIPS 201, SP 800-53, SP 800-40, SP 800-184 and NIST, *Framework for Improving Critical Infrastructure Cybersecurity*.

Additional details about the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block are available at: <https://www.nccoe.nist.gov/sites/default/files/library/project-descriptions/ch-pe-project-description-draft.pdf>.

NIST cannot guarantee that all of the products proposed by respondents will be used in the demonstration. Each prospective participant will be expected to work collaboratively with NIST staff and other project participants under the terms of the consortium CRADA in the development of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block. Prospective participants' contribution to the collaborative effort will include assistance in establishing the necessary interface functionality, connection and set-up capabilities and procedures, demonstration harnesses, environmental and safety conditions for use, integrated platform user instructions, and demonstration plans and scripts necessary to demonstrate the desired capabilities. Each participant will train NIST personnel, as necessary, to operate its product in capability demonstrations. Following successful demonstrations, NIST will publish a description of the security platform and

its performance characteristics sufficient to permit other organizations to develop and deploy security platforms that meet the security objectives of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block. These descriptions will be public information.

Under the terms of the consortium CRADA, NIST will support development of interfaces among participants' products by providing IT infrastructure, laboratory facilities, office facilities, collaboration facilities, and staff support to component composition, security platform documentation, and demonstration activities.

The dates of the demonstration of the Critical Cybersecurity Hygiene: Patching the Enterprise Building Block capability will be announced on the NCCoE website at least two weeks in advance at <http://nccoe.nist.gov/>. The expected outcome of the demonstration is to improve enterprise patching practices for general IT systems as part of a crucial effort in maintaining a highly effective Critical Cybersecurity Hygiene within the enterprise. Participating organizations will gain from the knowledge that their products are interoperable with other participants' offerings.

For additional information on the NCCoE governance, business processes, and NCCoE operational structure, visit the NCCoE website <http://nccoe.nist.gov/>.

Kevin A. Kimball,
NIST Chief of Staff.

[FR Doc. 2019-02977 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-13-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG828

Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of public meetings.

SUMMARY: The Pacific Fishery Management Council (Pacific Council) and its advisory entities will hold public meetings.

DATES: The Pacific Council and its advisory entities will meet April 9-16, 2019. The Pacific Council meeting will begin on Thursday, April 11, 2019 at 9 a.m. Pacific Daylight Time (PDT),

reconvening at 8 a.m. each day through Monday, April 15, 2019. All meetings are open to the public, except a closed session will be held from 8 a.m. to 9 a.m., Thursday, April 11 to address litigation and personnel matters. The Pacific Council will meet as late as necessary each day to complete its scheduled business.

ADDRESSES: Meetings of the Pacific Council and its advisory entities will be held at the Doubletree by Hilton Sonoma, One Doubletree Drive, Rohnert Park, CA; telephone: (707) 584-5466.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220. Instructions for attending the meeting via live stream broadcast are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Tracy, Executive Director; telephone: (503) 820-2280 or (866) 806-7204 toll-free; or access the Pacific Council website, <http://www.pcouncil.org> for the current meeting location, proposed agenda, and meeting briefing materials.

SUPPLEMENTARY INFORMATION: The April meeting of the Pacific Council will be streamed live on the internet. The broadcasts begin initially at 9 a.m. PDT Thursday, April 11, 2019 and continue at 8 a.m. daily through Monday, April 15, 2019. Broadcasts end daily at 5 p.m. PDT or when business for the day is complete. Only the audio portion and presentations displayed on the screen at the Pacific Council meeting will be broadcast. The audio portion is listen-only; you will be unable to speak to the Pacific Council via the broadcast. To access the meeting online, please use the following link: <http://www.gotomeeting.com/online/webinar/join-webinar> and enter the April Webinar ID, 634-645-459, and your email address. You can attend the webinar online using a computer, tablet, or smart phone, using the GoToMeeting application. It is recommended that you use a computer headset to listen to the meeting, but you may use your telephone for the audio-only portion of the meeting. The audio portion may be attended using a telephone by dialing the toll number 1-562-247-8422 (not a toll-free number), audio access code 532-691-006, and entering the audio pin shown after joining the webinar.

The following items are on the Pacific Council agenda, but not necessarily in this order. Agenda items noted as "Final Action" refer to actions requiring the Council to transmit a proposed fishery management plan, proposed plan amendment, or proposed regulations to

the U.S. Secretary of Commerce, under Sections 304 or 305 of the Magnuson-Stevens Fishery Conservation and Management Act. Additional detail on agenda items, Council action, advisory entity meeting times, and meeting rooms are described in Agenda Item A.4, Proposed Council Meeting Agenda, and will be in the advance April 2019 briefing materials and posted on the Pacific Council website at www.pcouncil.org no later than Friday, March 22, 2019.

Call to Order

Opening Remarks
Roll Call
Executive Director's Report
Approve Agenda

Open Comment Period

Comments on Non-Agenda Items

Coastal Pelagic Species Management

National Marine Fisheries Service Report
2019 Exempted Fishing Permits (EFPs)—Final Approval
Pacific Sardine Assessment, Harvest Specifications, and Management Measures—Final Action
Central Subpopulation of Northern Anchovy Management and Litigation Response—Final Action

Habitat

Current Habitat Issues

Administrative Matters

National Marine Sanctuaries
Coordination Report
Legislative Matters
Preliminary Allocation Review
Procedures
Fiscal Matters
Membership Appointments, Statement of Organization, Practices and Procedures and Council Operating Procedures
Future Council Meeting Agenda and Workload Planning

Salmon Management

Tentative Adoption of 2019 Management Measures for Analysis
Clarify Council Direction on 2019 Management Measures
Rebuilding Plans Update
Review of 2018 Fisheries and Summary of 2019 Stock Forecasts
Methodology Review Preliminary Topic Selection
Further Direction on 2019 Management Measures
Final Action on 2019 Management Measures

Groundfish Management

National Marine Fisheries Service Report
Cost Recovery Report
Vessel Movement Monitoring Update
Endangered Species Act Mitigation Measures for Seabirds—Preliminary Preferred Alternative

Science Improvements and Methodology Review
Endangered Species Act Mitigation Measures for Salmon—Range of Alternatives/Preliminary Preferred Alternative
Amendment 26: Blackgill Rockfish—Final Action
Electronic Monitoring: Implementation Update and 3rd Party Transition Plan
Inseason Adjustments—Final Action
Pacific Halibut Management
Incidental Catch Limits for 2019 Salmon Troll Fishery—Final Action

Advisory Body Agendas

Advisory body agendas will include discussions of relevant issues that are on the Pacific Council agenda for this meeting, and may also include issues that may be relevant to future Council meetings. Proposed advisory body agendas for this meeting will be available on the Pacific Council website <http://www.pcouncil.org/council-operations/council-meetings/current-briefing-book/> no later than Friday, March 22, 2019.

Schedule of Ancillary Meetings

Day 1—Tuesday, April 9, 2019

Coastal Pelagic Species Management Team—8 a.m.

Day 2—Wednesday, April 10, 2019

Coastal Pelagic Species Advisory Subpanel—8 a.m.
Coastal Pelagic Species Management Team—8 a.m.
Groundfish Electronic Monitoring Policy Advisory Committee—8 a.m.
Groundfish Electronic Monitoring Technical Advisory Committee—8 a.m.
Habitat Committee—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Scientific and Statistical Committee—8 a.m.
Budget Committee—10 a.m.
Model Evaluation Workgroup—10 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 3—Thursday, April 11, 2019

California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Coastal Pelagic Species Advisory Subpanel—8 a.m.
Coastal Pelagic Species Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Scientific and Statistical Committee—8 a.m.
Enforcement Consultants—3 p.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc

Day 4—Friday, April 12, 2019

California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.

Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc
Enforcement Consultants—Ad Hoc

Day 5—Saturday, April 13, 2019

California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc
Enforcement Consultants—Ad Hoc

Day 6—Sunday, April 14, 2019

California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc
Enforcement Consultants—Ad Hoc

Day 7—Monday, April 15, 2019

California State Delegation—7 a.m.
Oregon State Delegation—7 a.m.
Washington State Delegation—7 a.m.
Groundfish Advisory Subpanel—8 a.m.
Groundfish Management Team—8 a.m.
Salmon Advisory Subpanel—8 a.m.
Salmon Technical Team—8 a.m.
Tribal Policy Group—Ad Hoc
Tribal and Washington Technical Group—Ad Hoc
Enforcement Consultants—Ad Hoc

Day 8—Tuesday, April 16, 2019

Salmon Technical Team—8 a.m.

Although non-emergency issues not contained in this agenda may come before the Pacific Council for discussion, those issues may not be the subject of formal Council action during this meeting. Council 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 Pacific Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris

Kleinschmidt at (503) 820-2411 at least 10 business days prior to the meeting date.

Dated: February 14, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-02872 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG826

Caribbean 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 Caribbean Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) and Districts Advisory Panels (DAPs) will hold a 3-day joint meeting, in March, to discuss the items contained in the agenda in the **SUPPLEMENTARY INFORMATION**.

DATES: The meetings will be held on March 26, 2019, from 9 a.m. to 5 p.m., March 27, 2019, from 9 a.m. to 5 p.m., and March 28, 2019, from 9 a.m. to 5 p.m.

ADDRESSES: The meetings will be held at the Embassy Suites Hotel, Tartak St., Isla Verde, Carolina, Puerto Rico.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918-1903, telephone: (787) 766-5926.

SUPPLEMENTARY INFORMATION: The agenda for the meeting is the following:

March 26, 2019, 9 a.m.–12 p.m.

DAPs/SSC

- Call to Order and Welcome—Miguel A. Rolón
- SSC and DAP Members as Resources for Outreach and Education for the Stakeholders—Alida Ortíz
- Using Conceptual Models in an Ecosystem-Based Fisheries Management Framework
- Review of Ecosystem Conceptual Model and Applications
- Application for Risk Assessment
- DAPs and SSC Breakout Sessions to Populate Island-Based Conceptual Models

12 p.m.–1:30 p.m.

—Lunch Break

1:30 p.m.–5 p.m.

—DAPs and SSC Continuation of Breakout Sessions

March 27, 2019, 9 a.m.–10:30 a.m.

DAPs

—Continuation of DAPs Breakout Sessions

10:45 a.m.–12 p.m.

—DAPs Chairs Reports to the Plenary

12 p.m.–1:30 p.m.

—Lunch Break

1:30 p.m.–5 p.m.

SSC

—Review Conceptual Model Outcomes

—Refine Risk Assessment Tables Based on Island-Based Conceptual Model Outcomes

—Populate Risk Assessment Table

March 28, 2019, 9 a.m.–5 p.m.

SSC

—Populate Risk Assessment Tables

—Develop Recommendations to CFMC

—Other Business

The order of business may be adjusted as necessary to accommodate the completion of agenda items. The meeting will begin on March 26, 2019 at 9 a.m. and will end on March 28, 2019 at 5 p.m. Other than the start time, interested parties should be aware that discussions may start earlier or later than indicated. In addition, the meeting may be extended from, or completed prior to the date established in this notice.

Special Accommodations

These meetings are physically accessible to people with disabilities. For more information or request for sign language interpretation and other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico, 00918-1903, telephone: (787) 766-5926, at least 5 days prior to the meeting date.

Dated: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-02962 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****Submission for OMB Review; Comment Request**

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Evaluation of the Pacific Islands Managed and Protected Area Community (PIMPAC).

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Request: Regular submission (request for a new information collection).

Number of Respondents: 80.

Average Hours per Response: 1 hour per interview.

Burden Hours: 80.

Needs and Uses: The aim of the evaluation is to understand the effectiveness of the capacity development efforts of the Pacific Islands Managed and Protected Area Community, as known as PIMPAC. The survey will assess to what extent PIMPAC has developed human and organizational capacities to enhance protected area management in the Pacific island region. The survey will be used to interview primarily partners working at Not-for-profit organizations, state and federal agencies in the U.S. Pacific Affiliated Flag Islands of Hawaii, Guam, the Central Northern Marianas Islands, the Republic of Palau, the Federated States of Micronesia and the Republic of the Marshall Islands. Results of the survey are expected to help guide and improve the effectiveness of capacity development activities by PIMPAC for protected area management in the next ten years.

Affected Public: Federal Government, Not-for-profit institutions, State, and Governments in the U.S. Flag Islands and Freely Associated States.

Frequency: Once.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this

notice to OIRA_Submission@omb.eop.gov or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2019–02972 Filed 2–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XG804

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 and a half day in-person meeting of its Standing, Reef Fish, Mackerel, Shrimp and Socioeconomic Scientific and Statistical Committees (SSC).

DATES: The meeting will convene at 8:30 a.m. on Wednesday, March 13, 2019 and adjourn by 12 noon, EDT on Thursday, March 14, 2019.

ADDRESSES: The meeting will be held at the Gulf Council's office; see address below.

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Ryan Rindone, Fishery Biologist, Gulf of Mexico Fishery Management Council; ryan.rindone@gulfcouncil.org; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Wednesday, March 13, 2019; 8:30 a.m.–5 p.m.

The meeting will begin with Introductions, Adoption of Agenda, and Approval of Scientific and Statistical Committees (SSC) Minutes from the January 9, 2018 Standing, Reef Fish, and Mackerel SSC meeting; and, selection of SSC representative to attend the April 1–4, 2019 Council meeting in Biloxi, MS. The committees will review the SSC Operating Procedures; Stock Assessment Prioritization Tool; Updated Gray Snapper Projections at F_{26%SPR}; and, the Gulf Sector Allocations.

The committees will discuss Reef Fish and Coastal Migratory Pelagics Fishery Management Plans (FMP) Objectives; review the Generic Annual Catch Limit

(ACL) Carryover Amendment; receive an update on the NOAA RESTORE Activities; discuss the revisions to the Acceptable Biological Catch (ABC) Control Rule; and, select SSC volunteer members to participate on SEDAR 68: Scamp Data Workshop.

Thursday, March 14, 2019; 8:30 a.m.–12 p.m.

The committees will review the Stock Status for the Gulf of Mexico Shrimp Species; Marine Recreational Information Program (MRIP) data integration for Gulf Red Snapper; SEDAR Stock Assessment Executive Summary Components; and, discuss any other business items.

—Meeting Adjourns—

The meeting will be broadcast via webinar. You may register for listen-in access by visiting www.gulfcouncil.org and clicking on the SSC meeting on the calendar.

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: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–02958 Filed 2–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XG825

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a meeting.

DATES: The meeting will be held on Tuesday, March 19, 2019, from 1 p.m. to 5:30 p.m. and on Wednesday, March 20, 2019 from 9 a.m. to 12 p.m. See

SUPPLEMENTARY INFORMATION for agenda details.

ADDRESSES: The meeting will take place at the Hyatt Place Inner Harbor, 511 South Central Avenue, Baltimore, MD 21201; telephone: (410) 558–1840.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: www.mafmc.org.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to review the most recent survey and fishery data and the currently implemented 2020 acceptable biological catch (ABC) for golden and blueline tilefish. The SSC will also review and provide feedback on the most recent Mid-Atlantic State of the Ecosystem report, other Ecosystem Approach to Fisheries Management (EAFM) related activities and the Council's Comprehensive Research Plan. The SSC will review changes to the stock assessment schedule and peer review process for Mid-Atlantic and New England species as recently approved by the Northeast Regional Coordinating Council (NRCC). The SSC will also review and discuss recent activities by the Northeast Trawl Advisory Panel (NTAP). In addition, the SSC may take up any other business as necessary.

A detailed agenda and background documents will be made available on the Council's website (www.mafmc.org) prior to the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–02961 Filed 2–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XG827

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of telephonic meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Fishery Monitoring Advisory Committee Subgroup will hold a teleconference on March 27, 2019.

DATES: The teleconference will be held on Wednesday, March 27, 2019 from 12 p.m. to 4 p.m., Alaska Standard Time.

ADDRESSES: The meeting will be held telephonically. Teleconference number: (907) 271–2896.

Council address: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252; telephone: (907) 271–2809.

FOR FURTHER INFORMATION CONTACT: Elizabeth Figus, Council staff; telephone: (907) 271–2801.

SUPPLEMENTARY INFORMATION:

Agenda

Wednesday, March 27, 2019

The agenda will be to: Finalize recommendations for how to potentially lower costs and increase observer coverage rates in the partial coverage observer category for groundfish and halibut fisheries, while maintaining: the data sufficient for managing the fisheries; randomized deployment; and, cost equity considerations among participants. This may include providing input on differential deployment base levels by gear type. If time allows, the subgroup may also discuss recommendations of the Observer Fee Analysis Initial Review

document and other items at the discretion of the Chair.

The Agenda is subject to change, and the latest version will be posted at www.npfmc.org prior to the meeting, along with meeting materials.

Public Comment

Public comment letters will be accepted and should be submitted either electronically to Elizabeth Figus, Council staff: Elizabeth.figus@noaa.gov or through the mail: North Pacific Fishery Management Council, 605 W 4th Ave., Suite 306, Anchorage, AK 99501–2252.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019–02963 Filed 2–20–19; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XG823

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 (webinar).

SUMMARY: The Gulf of Mexico Fishery Management Council will convene a public hearing via webinar to discuss Shrimp Amendment 18—Evaluation of Shrimp Effort Threshold Reduction in the Area Monitored for Juvenile Red Snapper Bycatch.

DATES: The webinar will be held Thursday, March 21, 2019, at 6 p.m. and will conclude no later than 9 p.m.

ADDRESSES: The public hearing meeting will be held via webinar. A public listening station is available at the Gulf Council office (address below).

Council address: Gulf of Mexico Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein, Public Information

Officer, Gulf of Mexico Fishery Management Council;
emily.muehlstein@gulfcouncil.org,
 telephone: (813) 348-1630.

SUPPLEMENTARY INFORMATION: Council staff will brief the public on the purpose and need of the amendment. The Council is currently considering increasing the amount of shrimp effort allowed in the special area that is monitored for juvenile red snapper bycatch. Analysis shows that the effort reduction threshold, which currently requires that shrimp effort in the area monitored for juvenile red snapper be 67 percent below the effort in the baseline years of 2001-03, can be reduced to 60 percent without affecting the rebuilding of the red snapper stock. The schedule is as follows:

Thursday, March 21, 2019; 6 p.m.-9 p.m.

The meeting will be broadcast via webinar. You may register for the webinar by visiting *www.gulfcouncil.org* and clicking on the meeting on the calendar. The agenda is subject to change, and the latest version along with other meeting materials will be posted on as they become available.

Dated: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-02959 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XG824

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council will hold a public meeting of the Northeast Regional Marine Fish Habitat Assessment—Steering Committee.

DATES: The meeting will be held on Friday, March 29, 2019, from 10 a.m. to 4 p.m. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: The meeting will take place at the Hilton Garden Inn BWI Airport, 1516 Aero Drive, Linthicum Heights, MD 21090; telephone (410) 691-0500.

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674-2331; website: *www.mafmc.org*.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526-5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fishery Management Council is holding a meeting of the Northeast Regional Marine Fish Habitat Assessment—Steering Committee to review a habitat science workplan. An agenda and background documents will be posted at the Council's website (*www.mafmc.org*) prior to the meeting.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526-5251, at least 5 days prior to the meeting date.

Dated: February 15, 2019.

Tracey L. Thompson,

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

[FR Doc. 2019-02960 Filed 2-20-19; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF EDUCATION

National Assessment Governing Board

AGENCY: National Assessment Governing Board, U.S. Department of Education.

ACTION: Announcement of open and closed meetings.

SUMMARY: This notice sets forth the agenda for the February 28-March 2, 2019 Quarterly Board Meeting of the National Assessment Governing Board (hereafter referred to as Governing Board). This notice provides information to members of the public who may be interested in attending the meeting or providing written comments related to the work of the Governing Board. Notice of this meeting is required under the Federal Advisory Committee Act (FACA).

DATES: The Quarterly Board Meeting will be held on the following dates:

- February 28, 2019 from 10:00 a.m. to 6:00 p.m.
- March 1, 2019 from 8:30 a.m. to 5:00 p.m.
- March 2, 2019 from 7:30 a.m. to 12:00 p.m.

ADDRESSES: The Ritz-Carlton Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Executive Officer/ Designated Federal Official for the Governing Board, 800 North Capitol Street NW, Suite 825, Washington, DC 20002, telephone: (202) 357-6938, fax: (202) 357-6945, email: *Munira.Mwalimu@ed.gov*.

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The Governing Board is established under the National Assessment of Educational Progress Authorization Act, Title III of Public Law 107-279.

The Governing Board is established to formulate policy for the National Assessment of Educational Progress (NAEP). The Governing Board's responsibilities include the following: Selecting subject areas to be assessed, developing assessment frameworks and specifications, developing appropriate student achievement levels for each grade and subject tested, developing standards and procedures for interstate and national comparisons, improving the form and use of NAEP, developing guidelines for reporting and disseminating results, and releasing initial NAEP results to the public.

February 28–March 2, 2019 Committee Meetings

The Governing Board's standing committees will meet to conduct regularly scheduled work based on agenda items planned for this Quarterly Board Meeting and follow-up items as reported in the Governing Board's committee meeting minutes available at <https://www.nagb.gov/governing-board/quarterly-board-meetings.html>.

Detailed Meeting Agenda: February 28, 2019

February 28: Committee Meetings

Assessment Development Committee: Closed Session: 10:00 a.m. to 1:30 p.m.; Open Session 1:30 p.m.–4:00 p.m.

Executive Committee: Open Session: 4:30 p.m. to 4:45 p.m.; Closed Session 4:45 p.m. to 5:55 p.m.; Open Session: 5:55 p.m.–6:00 p.m.

March 1: Full Governing Board and Committee Meetings

Full Governing Board: Open Session: 8:30 a.m. to 8:40 a.m.; Closed Sessions: 8:40 a.m. to 10:00 a.m.; 1:00 p.m.–4:45 p.m.; Open Session: 4:45 p.m.–5:00 p.m.
Committee Meetings: 10:20 a.m. to 12:50 p.m.

Assessment Development Committee: Open Session: 10:20 a.m. to 12:50 p.m.
Reporting and Dissemination: Open Session: 10:20 a.m. to 10:25 a.m.; Closed

Session: 10:25 a.m.–11:05 a.m.; Open Session: 11:05 a.m. to 12:50 p.m.

Committee on Standards, Design and Methodology: Open Session: 10:20 a.m. to 12:00 p.m.; Closed Session: 12:00 p.m.–12:50 p.m.

March 2: Full Governing Board and Committee Meetings:

Nominations Committee: Closed Session: 7:30 a.m. to 8:15 a.m.

Full Governing Board: Closed Session: 8:30 a.m. to 9:15 a.m.; Open Session: 9:30 a.m. to 10:45 a.m.; Closed Session: 10:45 a.m. to 11:45 a.m.; Open Session—11:45 a.m. to 12:00 p.m.

On Thursday, February 28, 2019, the Assessment Development Committee will meet in closed session from 10:00 a.m. to 1:30 p.m. and in open session from 1:30 p.m. to 4:00 p.m. During the closed session, the committee will review secure cognitive and contextual questionnaire items for the NAEP Assessments in Reading and Technology and Engineering Literacy. This meeting must be conducted in closed session because the test items and data are secure and have not been released to the public. Public disclosure of the secure test items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code.

During the open session scheduled from 1:30 p.m. to 4:00 p.m. the Assessment Development Committee will review contextual questionnaire items for NAEP Assessments in Reading, Mathematics, and Science.

On Thursday, February 28, 2019, the Executive Committee will convene from 4:30 p.m. to 6:00 p.m. The meeting will be conducted in closed session from 4:45 p.m. to 5:55 p.m. During the closed session, the Executive Committee will receive and discuss cost estimates and implications for implementing the Long-Term Trend (LTT) assessment in 2020 and the enacted NAEP Assessment Schedule. This meeting must be conducted in closed session because public disclosure of this information would likely have an adverse financial effect on the NAEP program by providing confidential cost details and proprietary contract costs of current NAEP contractors to the public. Discussion of this information would be likely to significantly impede implementation of a proposed agency action if conducted in open session. Such matters are protected by exemption 9(B) of section 552b of Title 5 U.S.C. In open session from 5:55 p.m. to 6:00 p.m. the Executive Committee

will take action on recommending the Governing Board add LTT assessment to be administered in 2020 for the NAEP Assessment Schedule.

On Friday, March 1, 2019, the Governing Board will meet in open session from 8:30 a.m. to 8:40 a.m. From 8:30 a.m. to 8:40 a.m. the Governing Board will review and approve the March 1–2, 2019 quarterly meeting agenda and meeting minutes from the November 2018 Quarterly Board Meeting. Thereafter the Governing Board Chair will provide remarks.

From 8:40 a.m. to 10:00 a.m. the Governing Board will receive a closed session briefing from Senate and House Congressional staff. The briefing will be on sensitive policy priorities being considered by the U.S. Congress that also have budget implications. These priority discussions relate to program funding areas which are confidential and cannot be discussed in open session. Premature disclosure would likely significantly frustrate implementation of legislative actions. Such matters are protected by Section 9(B) of section 552b(c) of Title 5 of the United States Code.

From 10:00 a.m. to 10:10 a.m., the standing committee chairs will provide a preview of the agenda items for the committee meetings. At 10:10 a.m., the Governing Board will recess for a 10 minute break. Thereafter, committee meetings will take place from 10:20 a.m. to 12:50 p.m.

The Assessment Development Committee will meet in open session from 10:20 a.m. to 12:50 p.m. The committee will receive an update on the NAEP Mathematics Assessment Framework and review contextual questionnaire items for the NAEP Assessments in Reading, Mathematics and Science and discuss ongoing committee work related to the Strategic Vision.

The Reporting and Dissemination Committee will meet in open session from 10:20 a.m. to 10:25 a.m. and thereafter in closed session from 10:25 a.m. to 10:40 a.m. to review secure items from the 2018 NAEP Technology and Literacy Assessment. This meeting must be conducted in closed session because the test items and data are secure and have not been released to the public. Public disclosure of the secure test items would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code. Following the closed session, the committee will meet in open session

from 10:40 a.m. to 12:50 p.m. to discuss ongoing committee work.

The Committee on Standards, Design and Methodology will meet in open session from 10:20 a.m. to 12:00 p.m. to discuss ongoing committee work. From 12:00 p.m. to 12:50 p.m. the committee will receive a closed session briefing on design and analysis plans for the NAEP Writing Assessment. This meeting must be conducted in closed session because the assessment data are secure and have not been released to the public. Public disclosure of the secure test items and data would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code.

Following the committee meetings and a 10 minute break, the Governing Board will convene in two closed session meetings.

The first closed session is scheduled from 1:00 p.m. to 2:30 p.m. to receive a briefing and discuss the 2018 NAEP Technology and Engineering Literacy Report Card for Grade 8. This meeting must be conducted in closed session because the data has not been released to the public. Public disclosure of the secure data would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code.

The Governing Board will then take a 15 minute break and reconvene in the second closed session from 2:45 p.m. to 4:45 p.m. The Governing Board will receive a briefing and discuss the NAEP Assessment Schedule and budget. This meeting must be conducted in closed session because discussions will involve reviewing independent government cost estimates for assessing various NAEP subjects on the assessment schedule. Public disclosure of the cost estimates would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code.

The Governing Board will then meet in open session from 4:45 p.m. to 5:00 p.m. to take action on the LTT Assessment Schedule. The March 1, 2019 session of the Governing Board meeting will adjourn at 5:00 p.m.

On Saturday, March 2, 2019, the Nominations Committee will meet in closed session from 7:30 a.m. to 8:15 a.m. to review and discuss the final slate of candidates for Governing Board vacancies for terms that begin on October 1, 2019. The Nominations

Committee's discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of section 552b(c) of Title 5 of the United States Code.

On March 2, 2019, the Governing Board will meet in closed session from 8:30 a.m. to 9:15 a.m. to take action on the Nomination Committee's recommendation on the final slate of candidates for Governing Board 2019 vacancies for submission to the Secretary of Education for consideration and appointment. The Governing Board's discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of section 552b(c) of Title 5 of the United States Code.

The Governing Board will then take a 15 minutes break and reconvene in open session from 9:30 a.m. to 10:15 a.m. to receive an update from the Chair of the Assessment Development Committee on the NAEP Reading Framework. Thereafter, the Governing Board will receive reports from its standing committees from 10:15 a.m. to 10:45 a.m. The Governing Board will take action on the charge to the NAEP Reading Framework Panels.

From 10:45 a.m. to 11:45 a.m. the Governing Board will meet in closed session to receive a briefing on plans for reporting results from the 2017 NAEP Writing Assessment. This meeting must be conducted in closed session because the assessment data are secure and have not been released to the public. Public disclosure of the secure test items and data would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of section 552b(c) of Title 5 of the United States Code.

The Governing Board will meet in open session from 11:45 a.m. to 12:00 p.m. During this session, the Chair will introduce the new Executive Director who will provide remarks. The March 2, 2019 session of the Governing Board meeting will adjourn at 12:00 p.m.

Access to Records of the Meeting: Pursuant to FACA requirements, the public may also inspect the meeting materials at www.nagb.gov beginning on Thursday, February 28, 2019, by 10:00 a.m. EST. The official verbatim transcripts of the public meeting sessions will be available for public

inspection no later than 30 calendar days following the meeting.

Reasonable Accommodations: The meeting site is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (e.g., interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice no later than 21 days prior to the meeting.

Written comments may be submitted electronically or in hard copy to the attention of the Executive Officer/ Designated Federal Official (see contact information noted above). Information on the Governing Board and its work can be found at www.nagb.gov.

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

Authority: Pub. L. 107-279, Title III—National Assessment of Educational Progress section 301.

Lisa Stooksberry,

Deputy Executive Director, National Assessment Governing Board (NAGB), U. S. Department of Education.

[FR Doc. 2019-02885 Filed 2-20-19; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2018-ICCD-0100]

Case Service Report (RSA 911); ED-2018-ICCD-0100; Correction

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Correction notice.

SUMMARY: On February 15, 2019, the U.S. Department of Education published a 30-day comment period notice in the **Federal Register** with FR DoC 2019-02373 seeking public comment for an

information collection entitled, "Case Service Report (RSA 911)".

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 15, 2019, in FR Doc 2019-02373, on page 4452, in the first column, the name and telephone number of the contact should be David Steele, 202-245-6520.

On page 4452, in the second column, the total estimated number of burden hours should be 34,446 hours.

On page 4452, in the third column, the language for the last paragraph of the Abstract section of the notice should read:

The revisions to this instrument include the removal of duplicative data elements as well as those not specifically required by statute or used for statutorily required activities. RSA is proposing to remove 94 elements from the current collection. RSA proposed the addition of 14 elements, 6 of which are related to adding a new service to track VR participant participation in Apprenticeships and Work Based Learning Experiences. RSA is also adding some elements at the request of VR agencies (e.g., Date of Initial IPE and Date of IPE Extension).

The PRA Clearance Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: February 15, 2019.

Stephanie Valentine,

PRA Clearance Coordinator, Information Collection Clearance Program, Information Management Branch, Office of the Chief Information Officer.

[FR Doc. 2019-02911 Filed 2-20-19; 8:45 am]

BILLING CODE 4000-01-P

DEPARTMENT OF EDUCATION

[Docket No.: ED-2018-ICCD-0100]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Case Service Report (RSA-911)

Correction

In notice document 2019-02373, appearing on page 4459, in the issue of Friday, February 15, 2019 make the following correction:

On page 4459, in the first column, in the **DATES** section, "February 15, 2019" should read, "March 18, 2019".

[FR Doc. C1-2019-02373 Filed 2-20-19; 8:45 am]

BILLING CODE 1301-00-D

DEPARTMENT OF ENERGY**Electricity Advisory Committee**

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Electricity Advisory Committee. The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Wednesday, March 13, 2019; 12:00 p.m.–6:00 p.m. EST; Thursday, March 14, 2019; 8:00 a.m.–12:00 p.m. EST.

ADDRESSES: National Rural Electric Cooperative Association, 4301 Wilson Blvd., Arlington, Virginia 22203 (Ballston Metro Stop).

FOR FURTHER INFORMATION CONTACT: Lawrence Mansueti, Designated Federal Officer, Office of Electricity, U.S. Department of Energy, Forrestal Building, Room 8G–017, 1000 Independence Avenue SW, Washington, DC 20585; Telephone: (202) 586–2588 or Email: lawrence.mansueti@hq.doe.gov.

SUPPLEMENTARY INFORMATION:

Purpose of the Committee: The Electricity Advisory Committee (EAC) was established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C., App. 2, to provide advice to the U.S. Department of Energy (DOE) in implementing the Energy Policy Act of 2005, executing the Energy Independence and Security Act of 2007, and modernizing the nation's electricity delivery infrastructure. The EAC is composed of individuals of diverse backgrounds selected for their technical expertise and experience, established records of distinguished professional service, and their knowledge of issues that pertain to electricity.

Tentative Agenda

March 13, 2019

12:00 p.m.–1:00 p.m. Registration
1:00 p.m.–1:20 p.m. Welcome, Introductions, Developments since the October 2018 Meeting
1:20 p.m.–1:50 p.m. Update on OE Programs and Initiatives
1:50 p.m.–2:20 p.m. Presentation: OE Activities Related to Data Analytics
2:20 p.m.–2:40 p.m. Break
2:40 p.m.–5:00 p.m. Panel Session: Value Proposition for Big Data Analytics
5:00 p.m.–5:15 p.m. Break
5:15 p.m.–5:45 p.m. Energy Storage Subcommittee Update

5:45 p.m.–6:00 p.m. Wrap-up and Adjourn Day 1

March 14, 2019

8:00 a.m.–8:10 a.m. Day 2 Opening Remarks
8:10 a.m.–8:50 a.m. Energy Sector Cybersecurity Activities in Federal Government
8:50 a.m.–11:00 a.m. Panel Session: Electric Sector Cybersecurity Preparedness: Separating Facts from Fear, Uncertainty and Doubt
11:00 a.m.–11:15 a.m. Break
11:15 a.m.–11:40 a.m. Smart Grid Subcommittee Update
11:40 a.m.–11:50 a.m. Public Comments
11:50 a.m.–12:00 p.m. Wrap-up and Adjourn

The meeting agenda may change to accommodate EAC business. For EAC agenda updates, see the EAC website at: <http://energy.gov/oe/services/electricity-advisory-committee-eac>.

Public Participation: The EAC welcomes the attendance of the public at its meetings. Individuals who wish to offer public comments at the EAC meeting may do so on Thursday, March 14, 2019, but must register at the registration table in advance. Approximately 10 minutes will be reserved for public comments. Time allotted per speaker will depend on the number who wish to speak but is not expected to exceed three minutes. Anyone who is not able to attend the meeting, or for whom the allotted public comments time is insufficient to address pertinent issues with the EAC, is invited to send a written statement identified by “Electricity Advisory Committee Open Meeting,” to Mr. Lawrence Mansueti at 202–586–1472 (Fax) or email: Lawrence.Mansueti@hq.doe.gov.

Minutes: The minutes of the EAC meeting will be posted on the EAC web page at <http://energy.gov/oe/services/electricity-advisory-committee-eac>. They can also be obtained by contacting Mr. Lawrence Mansueti at the address above.

Signed in Washington, DC, on February 14, 2019.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–02844 Filed 2–20–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY**Hydrogen and Fuel Cell Technical Advisory Committee: Correction**

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

ACTION: Notice of open meeting: Correction.

SUMMARY: The Department of Energy (DOE) published in the **Federal Register** on February 13, 2019, a notice of an open meeting for the Hydrogen and Fuel Cell Technical Advisory Committee. The notice is being corrected to change the date of the meeting. Agenda items stay the same.

Correction

In the **Federal Register** of February 13, 2019, in FR DOC. 2019–002184, on pages 3770–3771, please make the following corrections:

In the **DATES** heading, third column, first paragraph, first line, please remove, Monday, March 18, 2019; and replace with: Tuesday, March 19, 2019; 8:00 a.m.–6:30 p.m.

In the **SUPPLEMENTARY INFORMATION, Public Participation** heading, page 3771, first column, first paragraph, nineteenth line, please change date to March 19, 2019.

Signed in Washington, DC, on February 14, 2019.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2019–02845 Filed 2–20–19; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings**

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Number: PR19–37–000.
Applicants: Oasis Pipeline, LP.
Description: Tariff filing per 284.123(b),(e)+(g): Oasis Pipeline, LP Statement of Operating Conditions, Effective January 11, 2019 to be effective 1/11/2019.

Filed Date: 2/8/19.
Accession Number: 201902085113.
Comments Due: 5 p.m. ET 3/1/19.
284.123(g) Protests Due: 5 p.m. ET 4/9/19.

Docket Numbers: RP19–656–000.
Applicants: Midcontinent Express Pipeline LLC.

Description: § 4(d) Rate Filing: Housekeeping Filing February 2019 to be effective 4/1/2019.

Filed Date: 2/13/19.
Accession Number: 20190213–5009.
Comments Due: 5 p.m. ET 2/25/19.
Docket Numbers: RP19–657–000.

Applicants: Columbia Gas Transmission, LLC.

Description: § 4(d) Rate Filing: TCO Negotiated Rate Amds—VEPCO to be effective 2/13/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5103.

Comments Due: 5 p.m. ET 2/25/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 14, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–02888 Filed 2–20–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–55–000.

Applicants: Crystal Lake Wind, LLC, Crystal Lake Wind Energy I, LLC.

Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Crystal Lake Wind, LLC, et al.

Filed Date: 2/13/19.

Accession Number: 20190213–5102.

Comments Due: 5 p.m. ET 3/6/19.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG19–56–000.

Applicants: Waipio PV, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Waipio PV, LLC.

Filed Date: 2/13/19.

Accession Number: 20190213–5027.

Comments Due: 5 p.m. ET 3/6/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3048–008; ER15–2720–002.

Applicants: Longview Fibre Paper and Packaging, Inc., WestRock CP, LLC.

Description: Notice of Non-Material Change in Status of Longview Fibre Paper and Packaging, Inc., et al.

Filed Date: 2/12/19.

Accession Number: 20190212–5142.

Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: ER12–862–001.

Applicants: Power Supply Services LLC.

Description: Notice of change in status of Power Supply Services LLC.

Filed Date: 2/12/19.

Accession Number: 20190212–5143.

Comments Due: 5 p.m. ET 3/5/19.

Docket Numbers: ER19–67–001.

Applicants: NRG REMA LLC.

Description: Compliance filing: Reactive Service Rate Schedule Informational Filing to be effective 12/14/2018.

Filed Date: 2/13/19.

Accession Number: 20190213–5055.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–433–003.

Applicants: Union Electric Company.

Description: Tariff Amendment: Amendment to Rate Schedule No. 22 to be effective 12/1/2018.

Filed Date: 2/13/19.

Accession Number: 20190213–5060.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–997–000.

Applicants: Pinetree Power LLC.

Description: Supplement to February 6, 2019 Pinetree Power LLC tariff filing.

Filed Date: 2/13/19.

Accession Number: 20190213–5014.

Comments Due: 5 p.m. ET 2/27/19.

Docket Numbers: ER19–1036–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2019–02–13 Termination of SA 3160 ATC–WEPCo PCA (Somers) to be effective 2/14/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5013.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1037–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2019–02–13 SA 3245 ATC–CWP D–TIA to be effective 1/24/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5015.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1038–000.

Applicants: Tracel Energy Marketing Limited Partners.

Description: Tariff Cancellation: Notice of Cancellation to be effective 4/15/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5029.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1039–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to the Appeal Process in Bylaws Section 3.10 to be effective 4/14/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5030.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1040–000.

Applicants: Pacific Wind Lessee, LLC.

Description: § 205(d) Rate Filing: Revised Shared Transmission Facilities Agreement and Request for Waivers to be effective 2/14/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5079.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1041–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 4242, Queue Nos. Z1–092/AD1–142 to be effective 4/24/2018.

Filed Date: 2/13/19.

Accession Number: 20190213–5104.

Comments Due: 5 p.m. ET 3/6/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 13, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–02864 Filed 2–20–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings #1**

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC19–56–000.
Applicants: Tonopah Solar Energy, LLC.

Description: Application of Tonopah Solar Energy, LLC for Authorization under Section 203 and request for expedited treatment.

Filed Date: 2/13/19.

Accession Number: 20190213–5164.

Comments Due: 5 p.m. ET 3/6/19.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–738–006; ER10–1186 009; ER10–1329 009; ER11–3097 010.

Applicants: DTE Electric Company, DTE Energy Trading, Inc., DTE Energy Supply, Inc., St. Paul Cogeneration, LLC.

Description: Notice of Non-Material Change in Status of the DTE MBR Entities.

Filed Date: 2/13/19.

Accession Number: 20190213–5152.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–210–001.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Response to Commission's Jan 15, 2019 Deficiency Letter re: Maintenance Adder to be effective 4/15/2019.

Filed Date: 2/14/19.

Accession Number: 20190214–5103.

Comments Due: 5 p.m. ET 3/7/19.

Docket Numbers: ER19–1042–000.

Applicants: Valentine Solar, LLC.

Description: § 205(d) Rate Filing: Valentine Solar Concurrence to Shared Transmission Facilities Agreement to be effective 2/17/2019.

Filed Date: 2/13/19.

Accession Number: 20190213–5121.

Comments Due: 5 p.m. ET 3/6/19.

Docket Numbers: ER19–1043–000.

Applicants: Idaho Power Company.

Description: § 205(d) Rate Filing: Schedule 12 Update Regarding Real Power Losses for Dynamic Transfers to be effective 4/15/2019.

Filed Date: 2/14/19.

Accession Number: 20190214–5000.

Comments Due: 5 p.m. ET 3/7/19.

Docket Numbers: ER19–1044–000.

Applicants: Telocaset Wind Power Partners, LLC.

Description: Compliance filing: New eTariff Baseline Filing to be effective 12/27/2018.

Filed Date: 2/14/19.

Accession Number: 20190214–5032.

Comments Due: 5 p.m. ET 3/7/19.

Docket Numbers: ER19–1045–000.

Applicants: Midcontinent

Independent System Operator, Inc., Pioneer Transmission LLC.

Description: § 205(d) Rate Filing: 2019–02–14_SA 3138 Pioneer-DEI 1st Rev Interconnection Agreement to be effective 12/12/2018.

Filed Date: 2/14/19.

Accession Number: 20190214–5033.

Comments Due: 5 p.m. ET 3/7/19.

Docket Numbers: ER19–1046–000.

Applicants: Midcontinent

Independent System Operator, Inc., Otter Tail Power Company.

Description: § 205(d) Rate Filing: 2019–02–14_SA 3247 OTP-Crowned Ridge II FCA (BSSB Crossing) to be effective 3/1/2019.

Filed Date: 2/14/19.

Accession Number: 20190214–5049.

Comments Due: 5 p.m. ET 3/7/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 14, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–02889 Filed 2–20–19; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY**Federal Energy Regulatory Commission****Combined Notice of Filings**

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–653–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel Retention Rates—Spring 2019 to be effective 4/1/2019.

Filed Date: 2/12/19.

Accession Number: 20190212–5012.

Comments Due: 5 p.m. ET 2/25/19.

Docket Numbers: RP19–654–000.

Applicants: Iroquois Gas

Transmission System, L.P.

Description: § 4(d) Rate Filing: 021219

Negotiated Rates—Mercuria Energy America, Inc. H–7540–89 to be effective 2/15/2019.

Filed Date: 2/12/19.

Accession Number: 20190212–5019.

Comments Due: 5 p.m. ET 2/25/19.

Docket Numbers: RP19–655–000.

Applicants: Bear Creek Storage

Company, L.L.C.

Description: Compliance filing

Annual Report on Operational

Transactions 2019.

Filed Date: 2/12/19.

Accession Number: 20190212–5026.

Comments Due: 5 p.m. ET 2/25/19.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: February 13, 2019.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2019–02863 Filed 2–20–19; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9989–89–Region 5]

Request for Nominations to the Great Lakes Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for nominations to the Great Lakes Advisory Board.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is seeking nominations from a diverse range of qualified candidates who desire to serve as members of EPA's Great Lakes Advisory Board (GLAB). The GLAB is chartered to provide advice and recommendations to the EPA Administrator, through the Great Lakes National Program Manager, on matters related to the Great Lakes Restoration Initiative and on domestic matters related to the implementation of the Great Lakes Water Quality Agreement between the U.S. and Canada. It is anticipated that GLAB members will be selected by the summer of 2019.

DATES: Nominations must be dated March 25, 2019.

ADDRESSES: Submit nominations electronically with the subject line "GLAB Nomination 2019" to Barnes.Edlynzia@epa.gov. You may also submit nominations by regular mail to: Edlynzia Barnes, Designated Federal Officer, U.S. Environmental Protection Agency, Great Lakes National Program Office, 77 W Jackson Boulevard, (G-9J) Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Edlynzia Barnes, Designated Federal Officer, Great Lakes National Program Office, U.S. Environmental Protection Agency, 77 W Jackson Boulevard, (G-9J) Chicago, IL; telephone number: 312-886-6249; email address: Barnes.Edlynzia@epa.gov.

SUPPLEMENTARY INFORMATION:

Background: The GLAB has been re-established in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix 2, as amended) and 41 CFR 102-3.50(d). The Advisory Board will provide advice and recommendations on matters related to the Great Lakes Restoration Initiative. The Advisory Board will also advise on domestic matters related to implementation of the Great Lakes Water Quality Agreement between the U.S. and Canada.

The major objectives will be to provide advice and recommendations on:

- a. Great Lakes protection and restoration activities;
- b. Long term goals, objectives, and priorities for Great Lakes protection and restoration; and
- c. Other issues identified by the Great Lakes Interagency Task Force/Regional Working Group.

The GLAB is expected to meet in person or by electronic means (*e.g.*, telephone, videoconference, webcast, etc.) approximately two (2) times per year, or as otherwise needed and approved by the Designated Federal

Officer. In-person meetings will be held in the Great Lakes region.

Nominations: The GLAB will be composed of approximately fifteen (15) members who will serve as representative members of non-federal interests. In selecting members, EPA will consider candidates representing a broad range of Great Lakes stakeholders, including, but not limited to: Environmental groups; agricultural groups; industry and/or business groups; citizen groups; environmental justice groups; foundations; academia; and state, local and tribal governments. In selecting members, EPA will consider the differing perspectives and breadth of collective experience needed to address the GLAB's charter. Other criteria used to evaluate nominees will include:

- Experience with Great Lakes issues;
- Leadership and consensus-building experience in Great Lakes organizations, businesses, and workgroups;
- Membership in professional societies involved with Great Lakes issues;
- Academic leadership and expertise;
- Community leadership; and
- Representation of multiple constituencies within the Great Lakes basin.

In accordance with the October 31, 2017 EPA Administrator's Memo entitled *Strengthening and Improving Membership on EPA Federal Advisory Committees*, and to ensure the independence and integrity of Federal Advisory Committee members, no member of an EPA Federal Advisory Committee shall receive EPA grants, either as principal investigator or co-investigator. Nominees to the GLAB shall describe their EPA funding history and past, current, or planned activities as principle or co-principle investigators of EPA grants. [Note: This restriction and the related requirement to provide funding history and a description of activities does not apply to employees of state, tribal or local government agencies which have been recipients of EPA grants.]

The EPA welcomes and values diversity. To obtain nominations of diverse candidates, the agency encourages nominations of women and men of all racial and ethnic groups. All nominations with be fully considered, but applicants shall be aware of EPA's specific membership goals and criteria as outlined above.

How to Submit Nominations: Any interested person or organization may nominate qualified persons to be considered for appointment to the GLAB. Individuals may self-nominate. Nominations can be submitted in electronic format (preferred) or in hard

copy format (see **ADDRESSES** section above). To be considered, nominations should include:

- Current contact information for the nominee, including the nominee's name, organization (and position within that organization), current business address, email address and daytime phone number;
- A brief statement describing the nominee's interest in serving on the GLAB;
- A resume and a short biography (no more than two paragraphs) describing the professional and educational qualifications of the nominee, including a list of relevant activities and any current or previous service on federal advisory committees; and
- A description of the nominee's EPA grant funding history including current EPA grant activities if applicable. If this does not apply to the nominee, please provide a brief statement indicating so.
- *Optional:* Letter(s) of recommendation from a third party supporting the nomination. Letter(s) should describe how the nominee's experience and knowledge will bring value to the work of the GLAB.

To help the Agency evaluate the effectiveness of its outreach efforts, nominees are requested to use their submission packages to identify how they became aware of this request for nominations.

Dated: February 7, 2019.

Cathy Stepp,

Regional Administrator, Great Lakes National Program Manager.

[FR Doc. 2019-02989 Filed 2-20-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA R9-2018-17; FRL-9989-86-Region 9]

Notice of Proposed Good Samaritan Settlement Agreement and Order on Consent for Removal Action for the Corona/Twin Peaks Mine Site, Napa County, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: In accordance with the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended ("CERCLA"), notice is hereby given that the Environmental Protection Agency ("EPA"), has entered into a proposed settlement, embodied in an administrative Good Samaritan

Settlement Agreement and Order on Consent for Removal Action (“Settlement Agreement”), with Tuleyome. Under the Settlement Agreement, Tuleyome agrees to carry out a removal action that will include pilot studies to assess the effectiveness of various chemical amendments to address discharges from the Corona drainage tunnel, mine waste consolidation, and revegetation. The work will also include improvements to the existing infiltration trenches and construction of other surface water runoff controls.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: The Settlement Agreement is available for public inspection at the United States Environmental Protection Agency, Superfund Records Center, 75 Hawthorne Street, Room 3110, San Francisco, California 94105. Telephone: 415-947-8717. Comments should be addressed to Larry Bradfish, Assistant Regional Counsel, Office of Regional Counsel (ORC-3), U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105; or Email: bradfish.larry@epa.gov; and should reference the Corona Mine/Twin Peaks Mine Site, EPA R9-2018-17. EPA’s response to any comments received will be available for public inspection at the same address.

FOR FURTHER INFORMATION CONTACT: Larry Bradfish, Assistant Regional Counsel (ORC-3), Office of Regional Counsel, U.S. EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105; Email: bradfish.larry@epa.gov; Phone (415) 972-3934.

SUPPLEMENTARY INFORMATION: Notice of this proposed administrative settlement is made in accordance with the Section 122(i) of CERCLA. The Settlement Agreement concerns work to be done by Tuleyome, a non-labile party in connection with the Corona Mine/Twin Peaks Mine (“Site”), located in Napa County, California. Tuleyome is a non-profit volunteer organization focused on protecting the wild and agricultural heritage of the inner Coastal Range and Western Sacramento Valley California. Tuleyome maintains offices at 607 North Street, Woodland, CA 95695. Tuleyome certifies in the Settlement Agreement that it is not a liable party under CERCLA, and that it does not intend to acquire ownership in the Site. This Settlement Agreement falls under EPA’s Good Samaritan Initiative, which adopted CERCLA administrative tools including a model Administrative Settlement and Order on Consent (AOC). The purpose of these administrative tools is to reduce barriers

under CERCLA for non-labile volunteers to clean up orphan mine sites. The Corona Mine/Twin Peaks Mine Settlement Agreement is based on the updated 2018 model AOC, and has been vetted with EPA Headquarters Office of Site Remediation Enforcement. Parties to the Settlement Agreement include the EPA and Tuleyome.

The Site that is the subject of this Settlement Agreement includes 32 contiguous acres of land that has been disturbed from past mining efforts at the Corona and Twin Peaks mercury mines. The 32-acre project is located within a larger 328.8-acre area that is owned by Corona/Twin Peaks Historical Association LLC which obtained the property from the previous owner, John Livermore (deceased), in 2012. Under this Settlement Agreement, Tuleyome agrees to carry out a removal action involving pilot studies to assess the effectiveness of various chemical amendments to address discharges from the Corona Mine drainage tunnel, mine waste consolidation, and revegetation. The work will also include improvements to existing infiltration trenches and construction of other surface water runoff controls. Tuleyome has performed work at the Site since 2016 under oversight by the California Regional Water Quality Control Board, Central Valley Region.

The performance of this work by Tuleyome will be overseen by EPA. The settlement includes a covenant not to sue Tuleyome pursuant to Sections 106 or 107(a) of CERCLA. EPA will consider all comments received on the Settlement Agreement in accordance with the **DATES** and **ADDRESSES** sections of this Notice and may modify or withdraw its consent to the Settlement Agreement if comments received disclose facts or considerations that indicate that the settlement is inappropriate, improper, or inadequate.

Dated: February 6, 2019.

Enrique Manzanilla,

Director, Superfund Division, EPA Region 9.

[FR Doc. 2019-02999 Filed 2-20-19; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-9989-75-OGC]

Local Government Advisory Committee: Request for Nominations

AGENCY: Environmental Protection Agency.

ACTION: Notice of request for nominations.

SUMMARY: EPA’s LGAC is a federal advisory committee chartered in 1992 under the Federal Advisory Committee Act (FACA), Public Law 92-463, to advise the EPA Administrator “from the field” on a broad range of environmental issues impacting local governments. Current LGAC committee members, and future qualified nominees, hold either current elected or non-elected/appointed positions and possess leadership experience—whether managerial or technical/programmatic—in the following contexts: Small community or township government (under 10,000 population); moderate-size or large city government; county government; state government; and, tribal government.

This notice solicits nominations to fill 10–15 vacancies on EPA’s LGAC—currently comprised of 30 individuals. Vacancies are anticipated to be filled by May, 2019.

DATES: Nominations are reviewed on an ongoing basis. However, to be considered for May 2019 appointments, nominations should be submitted by March 15, 2019.

ADDRESSES: Submit nominations electronically to eargle.frances@epa.gov with a subject heading of ‘LGAC 2019 NOMINATION’. You may also submit nominations by mail to: M. Frances Eargle, LGAC Designated Federal Officer, Office of Congressional and Intergovernmental Relations (OCIR), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue NW (MC1301A), Washington, DC 20460. Non-electronic submissions must follow the same format and contain the same information.

FOR FURTHER INFORMATION CONTACT: M. Frances Eargle, Designated Federal Officer for the LGAC, U.S. EPA; telephone (202) 564-3115; email: eargle.frances@epa.gov.

SUPPLEMENTARY INFORMATION:

Nominations: The credentials of all applicants/nominees will be fully considered, but viable candidates must—at a minimum—fall within the vocational/experiential parameters outlined in the Summary above. In addition to experience in local and/or state government, additional criteria to be considered may include: Experience with public-private partnerships; coalition-building and grass-roots involvement; implementation of environmental regulatory programs, whether federally-delegated, state-required or locally-mandated, including permitting programs, Brownfields, Superfund clean-up, air and water quality, and solid waste management; and, rural and/or small community

economic development. Diversity in vocational/career background, including private sector/industry experience, agricultural sector experience, professional affiliations, and demonstrated familiarity with local, regional and national environmental issues, also may be considered.

LGAC members are appointed for 1–2 year terms and are eligible for reappointment. The Committee meets several times a year, and the Administrator may ask members to serve on Subcommittees and Workgroups to develop reports and recommendations to address specific policy issues. The average workload for members is approximately 5 to 8 hours per month. While EPA is unable to provide compensation for services, official Committee travel and related expenses (lodging, etc.) will be fully reimbursed.

Nominations can be submitted in electronic format (preferred) or in hard copy format (see **ADDRESSES** section above). To be considered, all nominations should include:

- Current contact information for the applicant/nominee, including name, organization (and position within that organization), current business address, email address, and daytime telephone number;
- Brief statement describing the nominee's interest in serving on the LGAC;
- Resume and short biography (no more than 2 paragraphs) describing professional, educational and other pertinent qualifications of the nominee, including a list of relevant activities as well as any current or previous service on advisory committees; and,
- Letter(s) of recommendation from a third party (or parties) supporting the nomination. Letter(s) should describe how the nominee's experience and knowledge will bring value to the work of the LGAC.

Other sources, in addition to this **Federal Register** notice, may be utilized in the solicitation of nominees. EPA expressly values and welcomes diversity. In an effort to obtain nominations of diverse candidates, the agency encourages nominations of women and men of all racial and ethnic groups. Individuals may self-nominate.

Dated: December 20, 2018.

Jack Bowles,

Director, State and Local Relations.

[FR Doc. 2019–03000 Filed 2–20–19; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; National Survey of Unbanked and Underbanked Households; Comment Request (3064–0167)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of an existing information collection for its sixth National Survey of Unbanked and Underbanked Households (Household Survey), currently approved under OMB Control No. 3064–0167. The Household Survey is scheduled to be conducted in partnership with the U.S. Census Bureau as a supplement to its June 2019 Current Population Survey (CPS). The survey seeks to measure and track economic inclusion among U.S. households, and to identify the factors that inhibit the participation of these households in the mainstream banking system and opportunities to expand the use of banking services among underserved consumers. The results of these ongoing surveys will help policymakers and bankers understand the issues and challenges underserved households perceive when deciding how and where to conduct financial transactions. On November 6, 2018, the FDIC requested comment for 60 days on a proposal to renew these information collections. The FDIC received two comments which are discussed below. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of this information collection, and again invites comment on the renewal.

DATES: Comments must be submitted on or before March 25, 2019.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <https://www.FDIC.gov/regulations/laws/federal>.
- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building

(located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to OMB control number 3064–0167. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Counsel, 202–898–3767, mcabeza@fdic.gov, MB–3007, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal To Renew the Following Currently Approved Collection of Information

Title: National Survey of Unbanked and Underbanked Households.

OMB Number: 3064–0167.

Frequency of Response: Once.

Affected Public: U.S. Households.

Estimated Number of Respondents: 40,000.

Average Time per Response: 9 minutes (0.15 hours) per respondent.

Estimated Total Annual Burden: 0.15 hours × 40,000 respondents = 6,000 hours.

General Description of Collection: The FDIC recognizes that public confidence in the banking system is strengthened when banks effectively serve the broadest possible set of consumers. As a result, the agency is committed to increasing economic inclusion in the financial mainstream by ensuring that all Americans have access to safe, secure, and affordable banking services. The National Survey of Unbanked and Underbanked Households is one contribution to this end.

The National Survey of Unbanked and Underbanked Households is also a key component of the FDIC's efforts to comply with a Congressional mandate contained in section 7 of the Federal Deposit Insurance Reform Conforming Amendments Act of 2005 ("Reform Act") (Pub. L. 109–173), which calls for the FDIC to conduct ongoing surveys "on efforts by insured depository institutions to bring those individuals and families who have rarely, if ever, held a checking account, a savings account or other type of transaction or check cashing account at an insured depository institution (hereafter in this section referred to as the 'unbanked') into the conventional finance system." Section 7 further instructs the FDIC to consider several factors in its conduct of the surveys, including: (1) "What cultural, language and identification issues as well as transaction costs

appear to most prevent ‘unbanked’ individuals from establishing conventional accounts’; and (2) ‘‘what is a fair estimate of the size and worth of the ‘‘unbanked’’ market in the United States.’’ The National Survey of Unbanked and Underbanked Households is designed to address these factors and provide a factual basis on the proportions of unbanked households. Such a factual basis is necessary to adequately assess banks’ efforts to serve these households as required by the statutory mandate. The National Survey of Unbanked and Underbanked Households is the only population-representative survey conducted at the national level that provides state-level estimates of the size and characteristics of unbanked and underbanked households for all 50 states and the District of Columbia.

The FDIC supplement collects nationally-representative data, not otherwise available, to measure and track economic inclusion, and assess the accessibility and sustainability of banking relationships. The survey identifies different banking status groups, including unbanked and underbanked consumers. In identifying underbanked consumers, the FDIC considers households that have bank accounts but also substantially rely on nonbank financial services to meet basic financial needs such as receiving income, paying bills, saving and storing money, and accessing basic consumer credit. There is an emphasis on services that are disproportionately relied on by the unbanked, and are provided by a company or firm, as opposed to those accessed informally through individuals. The survey captures the use of a range of bank and nonbank products, and other data to help assess the reasons why some households do not make greater use of mainstream banking services.

To obtain this information, the FDIC partners with the U.S. Census Bureau, which administers the Household Survey supplement (‘‘FDIC Supplement’’) to households that participate in the CPS. The supplement has been administered every other year since January 2009. The previous survey questionnaires and survey results can be accessed through the following link: <http://www.economicinclusion.gov/surveys/>.

Consistent with the statutory mandate to conduct the surveys on an ongoing basis, the FDIC already has in place arrangements for conducting the sixth Household Survey as a supplement to the June 2019 CPS.

However, prior to finalizing the next survey questionnaire, the FDIC seeks to

solicit public comment on whether changes to the existing instrument are desirable and, if so, to what extent. It should be noted that, as a supplement of the CPS survey, the Household Survey needs to adhere to specific parameters that include limits in the length and sensitivity of the questions that can be asked of CPS respondents. Interested members of the public may obtain a copy of the proposed survey questionnaire on the following web page: <https://www.fdic.gov/regulations/laws/federal/2018/2019-draft-household-survey-questionnaire.pdf>.

Comment Discussion

On November 23, 2018, the FDIC requested comment for 60 days on a proposal to renew the National Survey of Unbanked and Underbanked Households information collection.¹ The FDIC received two comments in response to this request. Both commenters were supportive of the survey effort. One did not provide specific suggestions about the survey. The other commenter suggested that the FDIC collect information on the types of activities that consumers conduct at bank branches. The FDIC is interested in better understanding consumers’ use of banking channels, including physical branch locations, and the 2019 survey includes questions on the use of bank tellers and the intensity of branch use. However, the suggested question detailing branch activities was long, with 14 answer options, and would not be feasible to implement given the survey administration methods (it is primarily telephone-based) and survey length constraints. The FDIC will consider how best to learn about consumers’ bank branch activities in future survey administrations and/or other research efforts.

Request for Comment

Comments are again invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC’s functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, on February 15, 2019.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2019–03001 Filed 2–20–19; 8:45 am]

BILLING CODE 6714–01–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 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.: 012426–003.

Agreement Name: The OCEAN Alliance Agreement.

Parties: American President Lines, Ltd., APL Co. Pte. Ltd., and CMA CGM S.A. (acting as a single party); COSCO Shipping Lines Co., Ltd. and COSCO Shipping Lines (Europe) GmbH (acting as a single party); Evergreen Line Joint Service Agreement, and OOCL (Europe) Limited and Orient Overseas Container Line Limited (acting as a single party).

Filing Party: Robert Magovern; Cozen O’Connor.

Synopsis: The Amendment revises Article 7 of the Agreement to extend the minimum term of the agreement through March 31, 2027.

Proposed Effective Date: 3/30/2019.

Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/1214>.

Agreement No.: 201290.

Agreement Name: Maersk/MSC/Zim USPNW Cooperative Working Agreement.

Parties: Maersk Line A/S; Mediterranean Shipping Company S.A.; and ZIM Integrated Shipping Services Ltd.

Filing Party: Wayne Rohde; Cozen O’Connor.

Synopsis: The Agreement authorizes the parties to operate a vessel string in the trade between ports in China, Japan, Taiwan, and South Korea on the one hand and ports in the State of Washington on the other hand. It also authorizes ZIM to exchange space on that string for space on another string operated by Maersk and MSC.

¹ 83 FR 55532 (November 6, 2018).

Proposed Effective Date: 2/14/2019.
Location: <https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/21334>.

Dated: February 15, 2019.

Rachel Dickon,
 Secretary.

[FR Doc. 2019-02975 Filed 2-20-19; 8:45 am]

BILLING CODE 6731-AA-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 18, 2019.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *First Keyes Bancshares, Inc., Keyes, Oklahoma;* to merge with S G Bancshares, Inc., and thereby indirectly acquire State Guaranty Bank, both of Okeene, Oklahoma.

2. *Seiling Bancshares, Inc., Seiling, Oklahoma;* to become a bank holding company by acquiring 100 percent of the voting shares of The Seiling State Bank, Seiling, Oklahoma.

Board of Governors of the Federal Reserve System, February 15, 2019.

Michele Taylor Fennell,
 Assistant Secretary of the Board.

[FR Doc. 2019-02970 Filed 2-20-19; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 7, 2019.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Robert Dawson, Longwood, Florida;* to acquire voting shares of Pathway Bancorp, Cairo, Nebraska, and thereby indirectly acquire control of Pathway Bank, Cairo, Nebraska.

Board of Governors of the Federal Reserve System, February 15, 2019.

Michele Taylor Fennell,
 Assistant Secretary of the Board.

[FR Doc. 2019-02969 Filed 2-20-19; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000-0066; Docket No. 2018-0003; Sequence No. 21]

Submission for OMB Review; Labor-Related Requirements

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding labor-related requirements.

DATES: Submit comments on or before March 25, 2019.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for GSA, Room 10236, NEOB, Washington, DC 20503. Additionally submit a copy to GSA by any of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the instructions on the site.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandel/IC 9000-0066, Labor-related Requirements.

Instructions: Please submit comments only and cite Information Collection 9000-0066, Labor-related Requirements, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Funk, Procurement Analyst, Office of Governmentwide Acquisition Policy, GSA, at telephone 202-357-5805, or email kevin.funk@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

This information collection requirement, OMB Control No. 9000-0066, currently titled "Professional Employee Compensation Plan," is proposed to be retitled "Labor-related Requirements," due to consolidation with currently approved information collection requirements OMB Control

Nos. 9000–0175, 9000–0089, 9000–0014, and 9000–0155.

This clearance covers the information that offerors and contractors must submit to comply with the following labor requirements in the Federal Acquisition Regulation (FAR):

1. 52.222–2, *Payment for Overtime Premiums*. Paragraph (b) of this clause requires a contractor requesting overtime premiums that exceed the amount specified in paragraph (a) of the clause to do the following: (1) Identify the work unit; *e.g.*, department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime; (2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule; (3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and (4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

2. 52.222–6, *Construction Wage Rate Requirements*, paragraph (c) requires the contractor to establish additional classifications, if any laborer or mechanic is to be employed in a classification that is not listed in the wage determination applicable to the contract. The contractor submits to the contracting officer a Standard Form (SF) 1444, *Request for Authorization of Additional Classification and Rate*, along with other pertinent data, containing the proposed additional classification and minimum wage rate including any fringe benefits payments. OMB control numbers 1235–0023, 1235–0008, and 1235–0018 account for records to be kept by employers under the Fair Labor Standards Act (FLSA), 29 CFR 516, which is the basic recordkeeping regulation for all the laws administered by the Department of Labor (DOL) Wage and Hour Division. 29 CFR 516, prescribes labor standards for federally financed and assisted construction contracts subject to the Davis-Bacon and Related Acts (DBRA), as well as labor standards for non-construction contracts subject to the Contract Work Hours and Safety Standards Act (CWHSSA).

3. 52.222–11, *Subcontracts (Labor Standards)*, requires contractors to submit SF 1413, *Statement and Acknowledgment*, for each subcontract for construction within the United States, including the subcontractor's

signed and dated acknowledgment that the required labor clauses have been included in the subcontract. DOL regulations at 29 CFR subpart 5.6 require Federal agencies to ascertain compliance with statutes such as the Wage Rate Requirements (Construction) (formerly known as the Davis-Bacon Act) (40 U.S.C. chapter 31), the Copeland Act (Anti-Kickback) (18 U.S.C. 874 and 40 U.S.C. 3145), and the Contract Work Hours and Safety Standards Act (40 U.S.C. 3701 *et seq.*)

4. 52.222–18, *Certification Regarding Knowledge of Child Labor for Listed End Products*, requires offerors to certify they will not supply an end product of a type identified on the DOL List of Products Requiring Contractor Certification as to Forced or Indentured Child Labor, or that the offeror will supply such product, but made a good faith effort to determine whether forced or indentured child labor was used to mine, produce, or manufacture any product furnished under the contract and is unaware of any such use of child labor. For solicitations for commercial items, the Certification Regarding Knowledge of Child Labor for Listed End Products is at paragraph (i) of the provision at 52.212–3, *Offeror Representations and Certifications—Commercial Items*. This requirement is necessary to comply with Executive Order 13126, *Prohibition of Acquisition of Products Produced by Forced or Indentured Child Labor*, signed by President Clinton on June 12, 1999.

5. 52.222–33, *Notice of Requirement for Project Labor Agreement*, and 52.222–34, *Project Labor Agreement*, require offerors (provision) to submit, and contractors (clause) to maintain, a copy of the project labor agreement (PLA). Agencies have discretion on whether or not to use a PLA in connection with large-scale construction contracts, valued at or above \$25M. Agencies may require the PLA be submitted: (1) When offers are due, (2) prior to award (by the apparent successful offeror), or (3) after award.

6. 52.222–46, *Evaluation of Compensation for Professional Employees*. This provision requires offerors to submit for evaluation a total compensation plan setting forth proposed salaries and fringe benefits for professional employees working on the contract. This is required for negotiated service contracts when the contract amount is expected to exceed \$700,000 and the service to be provided will require meaningful numbers of professional employees.

B. Public Comment

A 60-day notice was published in the **Federal Register** at 83 FR 53876, on October 25, 2018. No comments were received.

C. Annual Reporting Burden

1. 52.222–2, *Payment for Overtime Premiums*

Respondents: 2,098.
Responses per Respondent: 1.
Total Annual Responses: 2,098.
Hours per Response: 0.25.
Total Burden Hours: 525.

2. FAR 52.222–6 and SF 1444 *Request for Authorization of Additional Classification and Rate*

Respondents: 3,831.
Responses per Respondent: 2.
Total Annual Responses: 7,662.
Hours per Response: 0.5.
Total Burden Hours: 3,831.

3. FAR 52.222–11, *Subcontracts (Labor Standards)*, and SF 1413, *Statement and Acknowledgment*

Respondents: 36,553.
Responses per Respondent: 2.
Total Annual Responses: 73,106.
Hours per Response: 0.05.
Total Burden Hours: 3,655.

4. FAR 52.222–18 *Certification Regarding Knowledge of Child Labor for Listed End Products*

Respondents: 1,104.
Responses per Respondent: 1.
Total Annual Responses: 1,104.
Hours per Response: 0.18.
Total Burden Hours: 198.

5. FAR 52.222–33 and 52.222–34, *Project Labor Agreement*

Respondents: 45.
Responses per Respondent: 1.
Total Annual Responses: 45.
Hours per Response: 1.
Total Burden Hours: 45.

6. FAR 52.222–46 *Evaluation of Compensation for Professional Employees*

Respondents: 3,136.
Responses per Respondent: 3.
Total Annual Responses: 9,408.
Hours per Response: 1.3333.
Total Burden Hours: 12,544.

7. *Summary*.

Respondents: 46,767.
Total Annual Responses: 93,423.
Total Burden Hours: 20,798.
Obtaining Copies: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F

Street, NW, Washington, DC 20405, telephone 202-501-4755. Please cite OMB Control No. 9000-0066, Labor-related Requirements, in all correspondence.

Dated: February 15, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division,
Office of Governmentwide Acquisition Policy,
Office of Acquisition Policy, Office of
Governmentwide Policy.

[FR Doc. 2019-02990 Filed 2-20-19; 8:45 a.m.]

BILLING CODE 6820-EP-P

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Agency for Healthcare Research and
Quality**

**Supplemental Evidence and Data
Request on Use of Cardiac
Resynchronization Therapy: A
Systematic Review Update**

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Use of Cardiac Resynchronization Therapy: A Systematic Review Update*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before March 25, 2019.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Jenae Bennis, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the

Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Use of Cardiac Resynchronization Therapy: A Systematic Review Update*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Use of Cardiac Resynchronization Therapy: A Systematic Review Update*, including those that describe adverse events. The entire research protocol is available online at: <https://www.ahrq.gov/research/findings/ta/index.html>.

This is to notify the public that the EPC Program would find the following information on Use of Cardiac Resynchronization Therapy: A Systematic Review Update helpful:

A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that

are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

KQ1a: Is cardiac resynchronization therapy with defibrillator (CRT-D) effective in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF $\leq 35\%$ and a QRS duration $\geq 120\text{ms}$?

KQ1b: Does the effectiveness of cardiac resynchronization therapy with defibrillator (CRT-D) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ2: What are the adverse effects or complications associated with CRT-D implantation?

KQ3a: Is cardiac resynchronization therapy in the absence of defibrillator capacity (CRT-P) effective in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with LVEF $\leq 35\%$ and a QRS duration $\geq 120\text{ms}$?

KQ3b: Does the effectiveness of cardiac resynchronization therapy in the absence of defibrillator capacity (CRT-P) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ4: What are the adverse effects or complications associated with CRT-P implantation?

KQ5: What is the effectiveness of CRT-D versus CRT-P in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with LVEF \leq 35% and a QRS duration \geq 120ms?

KQ6: What are the adverse effects or complications associated with CRT-D versus CRT-P implantation?

KQ7a: What is the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) versus conventional CRT techniques in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF \leq 35% and a QRS duration \geq 120ms?

KQ7b: Does the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ8: What are the adverse effects or complications associated with alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)?

KQ9: What is the effectiveness of His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between \geq 36% to \leq 50% and atrioventricular block?

KQ10: What are the adverse effects or complications associated with His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between \geq 36% to \leq 50% and atrioventricular block?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s)

KQ1–KQ8: Subjects of age \geq 18, with a left ventricular ejection fraction \leq 35% and a QRS duration \geq 120 ms.

KQ9–10: Subjects of age \geq 18, with an LVEF between \geq 36% to \leq 50% and atrioventricular block [We will use a recently published systematic review to address KQs 9–10].

Interventions

- Cardiac resynchronization therapy with a defibrillator (CRT-D)
- Cardiac resynchronization without a defibrillator (CRT-P)
- Alternative cardiac resynchronization therapy alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)

Comparators

- CRT-D vs. implantable cardioverter defibrillator (ICD)
- CRT-P vs. optimal medical therapy
- CRT-D vs. CRT-P
- Alternative CRT techniques versus conventional CRT techniques

Outcomes

KQ1a, 3a, 5, and 7a (Effectiveness)

Clinical outcomes

- 6 minute hall walk distance
- Left ventricular end diastolic volume/ volume index
- Left ventricular end systolic volume/ volume index
- Left ventricular ejection fraction
- Packer Score ¹⁷

Quality of life

- Minnesota Living with Heart Failure Inventory Score
- Kansas City Cardiomyopathy Score
- SF-36

Health outcomes

- Hospitalizations for heart failure
- All-cause mortality

KQ2, KQ4, KQ6, and KQ8 (Harms)

- Procedure related complications
- Length of hospital stay
- Pneumothorax
- Pocket hematoma
- Device Infection
- Cardiac perforation/tamponade
- Lead dislodgement
- Ventricular arrhythmias
- Death (within a week)
- Inappropriate ICD shocks (CRT-D and alternative CRT-D techniques only)

KQ1b, KQ3b, 7b (Subgroups)

- Age
- Gender
- Cardiomyopathy subtype
- QRS morphology
- Left ventricular ejection fraction
- NYHA class
- Atrial fibrillation

Timing

KQ1a, 3a, 5, and 7a, (Effectiveness)

- Outcomes from CRT-D, CRT-P, and alternative CRT techniques at 3–6 months, 1 year, and \geq 2 year end-points

KQ2, 4, 6, and 8 (Harms)

- Outcomes from CRT-D, CRT-P, and alternative CRT techniques at any time point

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019-02985 Filed 2-20-19; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–19–19Sj; Docket No. CDC–2019–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), 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 Preventive Health and Health Services Block Grant Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC). This study will allow CDC to monitor awardees progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions.

DATES: CDC must receive written comments on or before April 22, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0004 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. CDC will post, without

change, all relevant comments to *Regulations.gov*.

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

Preventive Health and Health Services Block Grant (OMB No. 0920-0106, exp. 7/31/2019)—Extension—Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Preventive Health and Health Services Block Grant (PHHSBG), Public Law 102-531, Public Health Service Act, provides funds to 61 awardees (50 states, the District of Columbia, two American Indian Tribes, and eight U.S. territories) and provides funding to address locally-defined public health needs in innovative ways. Block Grants allow awardees to prioritize the use of funds to address leading causes of death and disability. Block Grant funding also provides awardees with the ability to respond rapidly to emerging health issues, including outbreaks of diseases or pathogens. The PHHS Block Grant program is authorized by sections 1901-1907 of the Public Health Service Act.

CDC currently collects information from Block Grant awardees to monitor their objectives and activities (Preventive Health and Health Services Block Grant, OMB No. 0920-0106, exp. 7/31/2019). Each awardee is required to submit an annual application for funding (Work Plan) that describes its objectives and the populations to be addressed, and an Annual Report that describes activities, progress toward objectives, and Success Stories which highlight the improvements Block Grant programs have made and the value of program activities. Information is submitted electronically through the web-based Block Grant Information Management System (BGMIS).

CDC PHHS Block Grant program has benefited from this system by efficiently collecting mandated information in a format that allows data to be easily retrieved in standardized reports. The electronic format verifies completeness of data at data entry prior to submission to CDC, reducing the number of re-submissions that are required to provide concise and complete information.

The Work Plan and Annual Report are designed to help Block Grant awardees attain their goals and meet reporting requirements specified in the program's

authorizing legislation. Each Work Plan objective is defined in SMART format (Specific, Measurable, Achievable, Realistic and Time-based), and includes a specified start date and end date. Block Grant activities adhere to the Healthy People (HP) framework established by the Department of Health and Human Services (HHS). The current version of the BGMIS associates each awardee-defined activity with a specific HP National Objective, and identifies the location where funds are applied.

There are no changes to the number of Block Grant awardees (respondents), or the estimated burden per response for the Work Plan or the Annual Report. The BGMIS does not collect data related to assessing aggregate outcomes. A separate information collection request, designed to assess cross-cutting outputs and outcomes resulting from Block Grant activities has been developed and is undergoing public comment.

Legislation requires awardees to be accountable for funds they receive by evaluating and reporting on program activities and health status on an annual basis. The BGMIS system allows CDC and awardees to measure performance, identifying the extent to which objectives were met and identifying the most highly successful program interventions. CDC requests OMB approval to continue the Block Grant information collection for three years. CDC will continue to use the BGMIS to monitor awardee progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions. There are no changes to the number of respondents or the estimated annual burden per respondent. The Work Plan and the Annual Report will be submitted annually. The estimated burden per response for the Work Plan is 20 hours and the estimated burden per response for the Annual Report is 15 hours. Participation in this information collection is required for Block Grant awardees. There are no costs to respondents other than their time. Awardees continue to submit Success Stories with their Annual Progress reports through BGMIS, without changes.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
	Work Plan	61	1	20	1,220
	Annual Report	61	1	15	915
Total	2,135

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

[FR Doc. 2019-02917 Filed 2-20-19; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2019-0003]

National Health and Nutrition Examination Survey (NHANES) DNA Specimens: Guidelines for Proposals To Use Samples and Cost Schedule

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces reopening of the National Center for Health Statistics' (NCHS) National Health and Nutrition Examination Survey (NHANES) DNA Specimen Repository for research proposals. Blood samples for DNA purification were collected from study participants, with their permission, during NHANES III (1991-1994), NHANES 1999-2000, NHANES 2001-02, NHANES 2007-08, NHANES 2009-10, and NHANES 2011-12 (Office of Management and Budget Control Numbers # 0920-0237/0920-0950). DNA samples are being made available to the research community for genetic testing. The information gained from research using these samples can be combined with the extensive amount of information available in NHANES which describes the prevalence/trends of disease, nutrition, risk behaviors, and environmental exposures in the US population.

A more complete description of this program follows.

FOR FURTHER INFORMATION CONTACT: NHANES Genetic Project Officer, Jody McLean M.P.H., Division of Health and

Nutrition Examination Surveys, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, MD 20782, Phone: 301-458-4683, Fax: 301-458-4029, Email: NHANESgenetics@cdc.gov.

Authority: Sections 301, 306 and 308 of the Public Health Service Act (42 U.S.C. 241, 2421 and 242m).

SUPPLEMENTARY INFORMATION:

Background

NHANES is a program of periodic surveys conducted by NCHS. Examination surveys conducted since 1960 by NCHS have provided national estimates of the health and nutritional status of the U.S. civilian non-institutionalized population. The goals of NHANES are (1) to estimate the number and percentage of people in the U.S. population and designated subgroups with selected diseases and risk factors for those diseases; (2) to monitor trends in the prevalence, awareness, treatment and control of selected diseases; (3) to monitor trends in risk behaviors and environmental exposures; (4) to analyze risk factors for selected diseases; (5) to study the relation among diet, nutrition and health; (6) to explore emerging public health issues and new technologies; and (7) to establish and maintain a national probability sample of baseline information on health and nutritional status.

The availability of the NHANES III DNA samples has been previously announced in 2002 (67 FR 51585), 2006 (71 FR 22248), 2007 (72 FR 59094), 2009 (74 FR 45644), 2010 (75 FR 32191) and 2016 (81 FR 69822). NHANES III Phase II DNA samples (1991-1994) are from participants ages 12 or older (see NHANES III DNA Samples section for a description). For details about available NHANES III non-genetic data see <https://www.cdc.gov/nchs/nhanes/nhanes3/default.aspx>.

Beginning in 1999, NHANES became a continuous, annual survey rather than a periodic survey. For a variety of reasons, including disclosure and reliability issues, the survey data are

released as public use data files every two years. In addition to the analysis of data from any two year cycle, it is possible to combine two cycles to increase sample size and analytic options. Blood samples for DNA purification were collected from participants ages 20 years and older in survey years 1999-2002 and 2007-12. DNA samples are available as collections from NHANES 1999-2002 (NHANES 1999-2000 and 2001-02 samples available as one collection), and NHANES two-year cycles 2007-08, 2009-10, and 2011-12 (see NHANES 1999-2002, 2007-08, 2009-10, and 2011-12 DNA samples section for a description). The availability of the NHANES 1999-2002 DNA samples has been previously announced (2007 [72 FR 59094], 2009 [74 FR 45644], 2010 [75 FR 32191], and 2016 [81 FR 69822]). The availability of the NHANES 2007-08 DNA samples has been previously announced (2009 [74 FR 45644], 2010 [75 FR 32191], and 2016 [81 FR 69822]). The availability of the NHANES 2009-10 DNA samples has been previously announced (2016 [81 FR 69822]). The data release cycle for the NHANES corresponding to the period in which samples were collected for DNA is described in the following web links: <https://www.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=1999>
<https://www.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2001>
<https://www.cdc.gov/nchs/nhanes/continuousnhanes/default.aspx?BeginYear=2007>
<https://www.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2009>
<https://www.cdc.gov/nchs/nhanes/ContinuousNhanes/Default.aspx?BeginYear=2011>

Identifiable health information collected in the NHANES is kept confidential. During the informed consent process, survey participants are assured that data collected will be used only for stated purposes and will not be disclosed or released to others without the consent of the individual in

accordance with section 308(d) of the Public Health Service Act (42 U.S.C. 242m). During NHANES III, participants 12 years and older (parent or guardian signed the consent form if the participant was under age 18 years) signed a consent form to store a sample of their blood for future research. In NHANES 1999–2002, 2007–08, 2009–10, and 2011–12 a separate consent form was signed by eligible participants who agreed to the storing of blood samples for future genetic research. DNA samples will be available for testing only from participants who consented to future research. Resulting data from DNA samples testing will be linked to the NCHS variables (public use and restricted) and available for analyses through an NCHS Research Data Center (RDC). Access to these data at an NCHS RDC is only through an approved proposal process mechanism to assure confidentiality.

Research Proposal

Note: The following proposal types differ from those used in previous announcements for use of NHANES DNA samples (2002 (67 FR 51585), 2006 (71 FR 22248), 2007 (72 FR 59094), 2009 (74 FR 45644), 2010 (75 FR 32191), and 2016 (81 FR 69822)).

Proposals testing a complete NHANES DNA collection of samples: NHANES III, 7,159 samples; NHANES 1999–2002, 7,839 samples; NHANES 2007–08, 4,612 samples; NHANES 2009–10, 4,893 samples; NHANES 2011–12, 4,147 samples.

Note: If the investigator would like to propose a subsample of the complete set please contact the NHANES Genetic Project Officer to discuss feasibility.

Proposals should investigate specific research hypotheses. The investigator must specify which DNA collection they are requesting and the tests to be conducted on DNA samples excluding tests that produce incidental findings. The investigator is required to include in the research proposal an analytic plan that includes a list of proposed NCHS variables (public use and restricted) that would be used for the data analyses. The investigator will conduct the tests of the approved variants or approved assays on NHANES DNA samples that are labeled with a lab identification number that is not directly linkable to the public use file and therefore, anonymous to the investigator. Investigators are required to provide the data obtained from DNA testing to Division of Health and Nutrition Examination Survey (DHANES)/NCHS for quality control assessment. Analysis and linkage of the

resulting data are conducted in the NCHS RDC via a separate proposal.

After the DHANES/NCHS has completed the initial quality control assessment, investigators will be given up to six months to conduct a comprehensive quality assurance review. The timeframe allowed for this review will depend on the number and characteristics of the tests submitted. At the completion of this review, the availability of the resulting data will be announced to the public on the NHANES website Genetic Variant Search: <http://www.nhgeneticvariant.com/>. The resulting data can be linked to other NCHS variables (public use and restricted) for secondary data analysis. For further information on available variant data visit: <http://www.cdc.gov/nchs/nhanes/biospecimens/dnaspecimens.htm#Genetic>.

DNA samples will be provided in 96 well plates to investigators and distributed as samples from a complete collection or from a subsample of a collection.

Proposals testing DNA samples already obtained from previous solicitations:

Investigators who have obtained NHANES DNA samples from previous solicitations and have sufficient DNA left may request to do additional tests on the remaining DNA. These proposals must be submitted and approved before the initial proposal expiration date. The investigator is required to specify the test to be conducted on the samples excluding tests that produce incidental findings. The investigator must also include in the research protocol an analytic plan that includes a list of proposed NCHS variables (public use and restricted) that would be used for the data analyses.

DNA Samples

These DNA samples (NHANES III, NHANES 1999–2002, NHANES 2007–08, NHANES 2009–10, and NHANES 2011–12) were processed by the Centers for Disease Control and Prevention (CDC), National Center for Environmental Health (NCEH), Division of Laboratory Sciences (DLS).

NHANES III DNA Samples

The laboratory will distribute aliquots (samples) of crude DNA lysates extracted from cell lines. DNA concentrations vary and are estimated to range from 7.5–65.0 ng/ μ L with an average of approximately four micrograms in 100 μ L. Samples will be provided in 96 well plates that are bar-coded and labeled with a readable identifier. Quality control samples (5%

of the total) will be sent at no charge, on separate plates as blind replicates. DNA samples are available from 7,159 NHANES III participants. Samples will be distributed in a total of 82 plates including four plates of quality control samples. NHANES III DNA samples are in limited supply and, thus, are not available as a partial set. Due to the method of extraction, NHANES III DNA samples are not appropriate for all projects and/or assays.

NHANES 1999–2002, 2007–08, 2009–10, 2011–12 DNA Samples

The laboratory will distribute aliquots of purified, high molecular DNA in normalized concentrations of 50.0 ng/ μ L. Some samples may fall below this threshold. A sample of 40 microliters of each samples will be supplied. The amount of DNA in each sample may vary but will be on average approximately two micrograms.

There are purified DNA samples from 7,839 NHANES 1999–2002 participants. These samples will be distributed into 90 plates including four plates of quality control samples.

There are purified DNA samples available from 4,612 NHANES 2007–08 participants. These will be distributed into approximately 54 plates including three plates of quality control samples.

There are purified DNA samples available from 4,893 NHANES 2009–10 participants. These will be distributed into 58 plates including approximately three additional plates of quality control samples.

There are purified DNA samples available from 4,147 NHANES 2011–12 participants. These will be distributed into 49 plates including approximately three additional plates of quality control samples.

Each 96 well plate will be bar-coded and labeled with a readable identifier. Quality control samples (5% of a collection) will be sent at no charge, on separate plates as blind replicates.

Proposed Cost Schedule for Providing NHANES DNA Samples

Costs are determined by NCHS and include costs incurred from the contracting DNA Repository and DHANES administrative costs. The fee covers the costs of materials, equipment, labor, proposal review, administration and space for storage. For more details see Table 1. In prior years, the DNA Repository was maintained by CDC. The DNA Repository is now maintained by a private contractor. The costs of contracting, along with annual inflation increases, are reflected in the proposed cost schedule.

Procedures for Proposals

The investigator should follow these instructions for preparation of proposals. Proposals must be written using the outline below.

Proposal timeline:

- *Submission of Proposals:* Can be submitted on an ongoing basis
- *Scientific Review:* Within two months of proposal submission
- *Institutional Review Date:* Within six weeks of final proposal acceptance
- *Notification of approval:* Approximately 30 days after Institutional Review
- *Anticipated distribution of samples:* Approximately 60 days after all approvals are obtained

Note: Timeframe may vary depending on the nature of the proposal and the results of each level of review. Unforeseen circumstances could result in a change to this schedule.

DNA Specimen Program will begin accepting research proposals on April 22, 2019.

In addition to the cover page, the research proposal should contain the title of the research project, the name, address, phone number and Email address of the lead investigator along with the name of the institution where the testing will be conducted. Office of Human Research Protections assurance numbers for the institutions in the research project should be included. CDC investigators need to include their Collaborative Institutional Training Initiative (CITI) training expiration date. Email submission of the proposal is required.

The proposals should be a maximum of 20 single-spaced typed pages, excluding figures and tables. Please use appendices sparingly.

Applications will have a Scientific Review by the Genetic Project Officer and the Technical Panel. The Technical Panel is comprised of two members: A Genetic Research Scientist and a Genetic Epidemiologist. The members review each proposal for scientific and technical merit.

After the proposal is approved by the Genetic Technical Panel and the Genetic Project Officer it will be submitted for Institutional Review. All proposals will undergo Institutional Review by the NCHS Human Subjects Contact and the NCHS Research Ethics Review Board (ERB) for any potential human subjects concerns to ensure appropriate human subjects protections are provided in compliance with 45 CFR 46, and by the NCHS Confidentiality Officer for disclosure risk. The ERB will review the proposal even if the investigator has received approval by their institutional review panel.

If a proposal is approved, the title, specific aims, name, and phone number of the author will be maintained by NCHS and released if requested by the public. Unapproved proposals will not be maintained by NCHS.

Proposals should include the following information:

(1) *Cover sheet:* Include the name of the institution where the test will be conducted and Office of Human Research Protections assurance numbers for the institutions engaged in the research project. CDC investigators need to include their CITI training expiration date.

(2) *Abstract:* Please limit the abstract to 300 words.

(3) *Specific Aims:* List the broad objectives; describe concisely and realistically what the research is intended to accomplish, and state the specific hypotheses to be tested.

(4) *Background and Public Health Significance:*

(A) Describe the public health significance of the proposed research.

(B) Discuss how the results will be used. Analyses should be consistent with the NHANES mission to assess the health of the nation. The Scientific Review will ensure that the proposed project does not go beyond either the general purpose for collecting the blood samples for DNA in the survey or the specific stated goals of the proposal.

(5) *Design, Method, and Data analysis:* The appropriateness and adequacy of the methodology proposed to reach the research aims, and the appropriateness of using the NHANES (a complex, multistage probability sample of the national population) to address the goals of the proposal will be assessed.

(A) *Research Design and Methods:* Describe the analytic and statistical methods to be employed. Include power calculations. For all proposal categories, include a detailed description of the laboratory methods. The characteristics of the laboratory assay, such as reliability, validity, should be included with appropriate references. The potential difficulties and limitations of the proposed procedures should also be discussed. Address adequate methods planned for handling and storage of DNA samples. Proposals *must* specify specific variants or the standard assay(s) that will be used to test the proposed research hypotheses and include a statement of why the specific standard assay(s) is/are necessary to test the proposed hypotheses. The standard assay is a commercially available assay for a curated set of variants. (1) Proposals will be provided with quality control samples at no additional cost.

Approved projects must run these quality control samples and submit these results along with the results from the NHANES DNA samples, unless the Genetic Project Officer has approved an alternative quality control review plan. (2) Proposals using residual samples should have residual quality control samples and investigators will be required to use these residual quality control samples. The proposal should address additional quality control procedures the laboratory will use to assure the validity of the test results and address adequate methods planned for handling and storage of sample.

(B) *Data analysis: Note: All resulting data are restricted access data and must be analyzed in the NCHS Research Data Center (RDC) Output:* Please describe the data output that you would like to retain and take out of the RDC after analyses.

(6) *Additional information for NHANES:*

(A) *Clinical Relevance of Research Findings:* The consent document for DNA samples storage and future studies states that individual results will not be provided to participants; therefore, no tests that would need to be reported back to the participant can be proposed. DHANES/NCHS will use the most recent American College of Medical Genetics and Genomics (ACMG) recommendations for reporting incidental findings to review the proposed tests and the potential incidental findings. Investigators must justify that the proposed tests do not produce sets of variants on specific genes listed by the most recent ACMG as reportable incidental findings and describe how potential incidental test results will be handled. As of its publication in February 2017, the most recent report, "Recommendations for reporting of secondary findings in Clinical Exome and Genome Sequencing, 2016 update (ACMG SF v2.0): A policy statement of the American College of Medical Genetics and Genomics", lists 59 genes where specific variants on these genes are pathogenic for 27 conditions.

(B) *Data Transfer:* Specify the secure method to transfer resultant data to NCHS. Investigators must use a device that meets federal information processing standards (FIPS 140-2 and FIPS 197).

(C) *Period of Performance:* Specify the project period. The period may be up to three years. At the end of the project period, any unused samples must be returned to the NHANES DNA Specimen Repository or destroyed by the investigator. Extensions to the

period of performance may be requested.

(D) *Funding*: Include the source and status of the funding to perform the requested laboratory analysis. Investigators will be responsible for the cost of processing and shipping the samples (*See table*).

(7) *References*

(8) *Resumes/CV*: Please include a 2-page CV for each member of the research team in this document (not as attachments).

Public Availability of Data

Data resulting from use of DNA samples will be made available to the public for secondary data analyses via the NCHS RDC. After DHANES/NCHS quality control assessment is completed, investigators will be given up to six months to conduct comprehensive quality assurance review in the NCHS RDC. The quality assurance review timeframe will be negotiated between the investigator and the NHANES Genetic Project Officer and will depend on the type, number, and characteristics of the tests submitted. The results of the quality assurance review will be provided to DHANES/NCHS and appropriate aspects will become part of the data set documentation. The public announcement, informing that test results are available for secondary data analyses after submission and acceptance of proposals, will occur once the quality assurance review timeframe has ended. For a list of currently available variant data see: <http://www.nhgeneticvariant.com/>.

Proposals for secondary data analyses linking NCHS restricted data, NCHS public use data, or non-NCHS data to data resulting from DNA sample testing will be reviewed by the NCHS RDC. See <http://www.cdc.gov/rdc> for proposal guidelines.

Submission of Proposals

Proposals can be submitted immediately. The review process will begin approximately 60 days from the publication of this notice and will include all proposals submitted as of that date.

Electronic submission of proposals is required. Please submit proposals to the NHANES Genetic Project Officer: Jody McLean M.P.H., Division of Health and Nutrition Examination Surveys, National Center for Health Statistics,

Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, MD 20782, Phone: 301-458-4683, Email: NHANESgenetics@cdc.gov.

Agency Agreement

Investigators must secure funding and sign terms and conditions agreements for the use of the DNA samples with CDC/NCHS prior to the release of the NHANES DNA samples. Investigators must agree to: (a) Use the samples only for the approved tests; (b) use the test results only for purposes as stated in the approved proposal; (c) not link the results of the proposed research to any other data; and (d) not use the DNA samples for commercial purposes, as set forth in a legally binding Materials Transfer Agreement (if non-government researchers) or Interagency Agreement (if government researchers). In addition, all investigators will be required to sign a Designated Agent Agreement (DAA) with CDC/NCHS in accordance with NCHS' confidentiality legislation, the Confidential Information Protection and Statistical Efficiency Act (CIPSEA; Title V of the E-Government Act of 2002 (Pub. L. 107-347)). The DAA is the mechanism by which CDC/NCHS may authorize designation of agents to exclusively perform activities needed to produce approved data on CIPSEA-protected NHANES DNA samples.

Approved Proposals: Post-Testing Procedures

After DNA samples are received and testing is complete, the investigator must send the resulting data back for DHANES/NCHS quality control(QC) assessment. While DHANES/NCHS QC assessment is under way, the investigator can submit a NCHS RDC proposal (<http://www.cdc.gov/rdc>) to conduct additional quality assurance review. Once the investigator's quality assurance review is complete and the results returned to DHANES/NCHS, the test results will be made available to the public. Data are made public through the NCHS RDC and at this point the investigator can submit an NCHS RDC proposal to request linkage to NCHS restricted data, NCHS public use data, or Non-NCHS data to conduct their analysis.

After the comprehensive quality assessment process has been completed

by the investigator, a list of variants generated from NHANES samples testing will be made available to the public for potential requests for proposals via NCHS RDC proposals. The list of variants will be available in the NHANES Genetic Variant Search (<http://www.nhgeneticvariant.com/>). In addition, DHANES/NCHS quality control assessment procedures will be posted on the NHANES Genetic Repository website and/or available via email.

Progress Reports

The investigator must submit a progress report in the annual CDC/NCHS/ERB continuation report. An ERB continuation form will be sent to the investigator each year for project update. If an approved proposal is unable to obtain funding the proposal will be closed.

Termination of ERB Protocol

At the end of laboratory testing the ERB Protocol will be closed.

Disposition of Results and Samples

The provided DNA samples cannot be used for any purpose other than the specifically requested purpose outlined in the proposal and approved through the Scientific and Institutional Review. No DNA samples can be shared with others, including other investigators, unless specified in the proposal and so approved. Samples must be returned upon completion of the approved project (or destroyed, but only with the written approval of the NHANES Genetic Project Officer). Test results from all studies using NHANES DNA samples will be made available to the public for secondary data analyses. After the DHANES/NCHS quality control assessment is completed, investigators will be given up to six months to conduct a more comprehensive quality assurance review. The final quality assurance review timeframe will be negotiated between the researcher and the NHANES Genetic Project Officer and characteristics of the tests submitted. Proposals for secondary data analyses will be reviewed by the NCHS RDC on a rolling basis; see: <http://www.cdc.gov/rdc> for proposal guidelines. All data analyses will be conducted via access modes available at NCHS RDC.

Total costs	1999–2002, 2007–08, 2009–10, 2011–12 complete set	1999–2002, 2007–08, 2009–10, 2011–12 partial set	NHANES III complete set
Materials and Equipment—contractor: Plates, reagents, assays, aliquoting and packaging samples; use of equipment	\$1.51	\$4.53	\$0.75
Labor—contractor: Processing, handling, and shipping; NCHS: Data quality control	4.98	24.90	2.49
Proposal review and Administrative expenses—contractor: Inventory management and reporting; NCHS: Management of proposal process non-NCHS: Technical panel fees	3.02	6.04	1.51
Space—contractor: Freezer use and maintenance	5.59	5.59	2.79
Cost per sample	15.10	41.06	7.55
Cost per new proposal:			
1999–2002	118,369	*
2007–2008	69,641
2009–2010	73,884
2011–2012	62,605	54,050
III
Cost per additional proposal:**			
1999–2002	5,918	***
2007–2008	3,633
2009–2010	3,694
2011–2012	3,131	2,702
III

* Cost calculated upon request.
 ** Additional research using DNA samples already obtained from previous solicitations.
 *** This charge will be 5 percent of the original cost.

Note: Applicable CDC overhead and NCHS management and oversight charges will be added to these rates for proposals coming from Federal agencies.

Dated: February 14, 2019.

Sandra Cashman,
 Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2019–02908 Filed 2–20–19; 8:45 am]
 BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

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, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and

Control Special Emphasis Panel (SEP)—RFA–CE–19–005, Research Grants for Preventing Violence and Violence Related Injury.

Date: May 14–15, 2019.

Time: 8:30 a.m.–5:30 p.m., EDT.

Place: Atlanta Marriott Buckhead and Conference Center, 3405 Lenox Road NE, Atlanta, GA 30326.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Mikel Walters, Ph.D., Scientific Review Official, NCIPC, CDC, 4770 Buford Highway NE, Mailstop F–63, Atlanta, Georgia 30341, Telephone (404) 639–0913, *MWalters@cdc.gov*.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,
 Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–02949 Filed 2–20–19; 8:45 am]
 BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—IP19–001, Surveillance for Respiratory Syncytial Virus (RSV) and Other Viral Respiratory Infections Among Native Americans/Alaskan Natives; IP19–002, Increasing Influenza and Tdap Vaccination of Pregnant Women in Obstetric/Gynecologic Practices in Large Health Systems Through Quality Improvement Interventions and IP19–003, Understanding and Improving Immunization Services Among Adult Hospital Inpatient and Observation/Clinical Decision Unit Settings; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—IP19–001, Surveillance for Respiratory Syncytial Virus (RSV) and Other Viral Respiratory Infections Among Native Americans/Alaskan Natives; IP19–002, Increasing Influenza and Tdap Vaccination of Pregnant Women in Obstetric/Gynecologic Practices in Large Health Systems through Quality Improvement Interventions and IP19–003, Understanding and Improving Immunization Services Among Adult Hospital Inpatient and Observation/Clinical Decision Unit Settings; March 19–20, 2019; 10:00 a.m.–5:00 p.m.,

(EDT) which was published in the **Federal Register** on November 26, 2018, Volume 83, Number 227, page 60427.

The meeting is being amended to change the date. The date should read as follows: March 20, 2019; 10:00 a.m.–5:00 p.m. The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30333, (404) 718–8833, gca5@cdc.gov. The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–02909 Filed 2–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PS19–003, Using Real-Time Prescription and Insurance Claims Data To Support the HIV Care Continuum; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PS19–003, Using Real-time Prescription and Insurance Claims Data to Support the HIV Care Continuum; March 6–7, 2019, 10:00 a.m.–5:00 p.m., (EST), Teleconference, Centers for Disease Control and Prevention, Room 1080, 8 Corporate Square Blvd., Atlanta, GA 30329 which was published in the **Federal Register** on December 26, 2018, Volume 83, Number 246, pages 66267.

The meeting is being amended to change the date. The date should read as follows: March 6, 2019; 10:00 a.m.–5:00 p.m. The meeting is closed to the public.

FOR FURTHER INFORMATION CONTACT:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30333, (404) 718–8833, gca5@cdc.gov.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019–02910 Filed 2–20–19; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10280]

Agency Information Collection Activities: Proposed Collection; Comment Request; Correction

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

ACTION: Correction of notice.

SUMMARY: This document corrects the information provided for [Document Identifier: CMS–10180] titled “Home Health Change of Care Notice.”

FOR FURTHER INFORMATION CONTACT:

William N. Parham, III, (410) 786–4669.

SUPPLEMENTARY INFORMATION:

I. Background

In the February 14, 2019, issue of the **Federal Register** (84 FR 7073), we published a Paperwork Reduction Act notice requesting a 30-day public comment period for the information collection request identified under CMS–10180, OMB control number 0938–1196, and titled “Home Health Change of Care Notice.”

II. Explanation of Error

In the February 14, 2019, notice, the information provided in the third column at the top of notice, on page 4073, was published with incorrect information in the “*Document Identifier*” section. This notice corrects the language found in the “*Document Identifier*” section under the third column at the top of notice, on page 4073 of the February 14th notice. Also in the February 14, 2019, notice, the information provided in the third column under paragraph 2, on page 7074, was published with incorrect information in the “*Form Number*.” This notice corrects the language found in the “*Form Number*” section under

the 2nd paragraph on page 7074 of the February 14th notice. All of the other information contained in the February 14, 2019, notice is now correct. The related public comment period remains in effect and ends March 18, 2019.

III. Correction of Error

In FR Doc. 2019–02235 of February 14, 2019 (84 FR 4073), page 7073, the language in the third column, at the top of the notice that begins with “[*Document Identifier*]” and ends with “and CMS–10440],” is corrected to read as follows:

[Document Identifier: CMS–10680, CMS–10280 and CMS–10440]

In FR Doc. 2019–02235 of February 14, 2019 (84 FR 4073), page 7074, the language in the third column, in the second paragraph in that column that begins with “*Form Number*” and ends with “Frequency: Reporting—Annually; Affected Public: State, Local or Tribal governments,” is corrected to read as follows:

Form Number: CMS–10280 (OMB control number: 0938–1196); Frequency: Reporting—Annually; Affected Public: State, Local or Tribal governments.

Dated: February 14, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–02793 Filed 2–20–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–179]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested

persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by March 25, 2019.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

2. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies

must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Medicaid State Plan Base Plan Pages; *Use:* State Medicaid agencies complete the plan pages while we review the information to determine if the state has met all of the requirements of the provisions the states choose to implement. If the requirements are met, we will approve the amendments to the state's Medicaid plan giving the state the authority to implement the flexibilities. For a state to receive Medicaid Title XIX funding, there must be an approved Title XIX state plan. *Form Number:* CMS-179 (OMB control number 0938-0193); *Frequency:* Occasionally; *Affected Public:* State, Local, and Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,120; *Total Annual Hours:* 22,400. (For policy questions regarding this collection contact Annette Pearson at 410-786-6958.)

Dated: February 15, 2019.
William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.
 [FR Doc. 2019-02996 Filed 2-20-19; 8:45 am]
BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No.: 0970-0379]

Proposed Information Collection Activity; Comment Request

Title: Project Outcome Assessment Survey.

Description: The information collected by the Project Outcome Assessment Survey is needed for two main reasons: (1) To collect crucial information required to report on the Administration for Native Americans' (ANA) established Government Performance and Results Act (GPRA) measures, and (2) to properly abide by ANA's congressionally-mandated statute (42 United States Code 2991 *et seq.*) found within the Native American Programs Act of 1974, as amended, which states that ANA will evaluate projects assisted through ANA grant dollars "including evaluations that describe and measure the impact of such projects, their effectiveness in achieving stated goals, their impact on related programs, and their structure and mechanisms for delivery of services." The information collected with this survey will fulfill ANA's statutory requirement and will also serve as an important planning and performance tool for ANA.

Respondents: Tribal Governments, Native American nonprofit organizations, and Tribal Colleges and Universities

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ANA Project Outcome Assessment Survey	85	1	6	510

Estimated Total Annual Burden Hours: 510.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment

on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research

and Evaluation, 330 C Street SW, Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) 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 within 60 days of this publication.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019-02915 Filed 2-20-19; 8:45 am]

BILLING CODE 4184-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-1939]

Use of Investigational Tobacco Products; Revised Draft Guidance for Industry and Investigators; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised draft guidance for industry and investigators entitled "Use of Investigational Tobacco Products." The revised draft guidance replaces the draft guidance of the same title announced in the **Federal Register** of September 24, 2015 (September 2015 draft guidance). The revised draft guidance, when finalized, will describe FDA's current thinking regarding the definition of "investigational tobacco product" and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy.

DATES: Submit either electronic or written comments on the draft guidance by April 22, 2019 to ensure that the Agency considers your comment on this

draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information by April 22, 2019.

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 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-2014-D-1939 for "Use of Investigational Tobacco Products; Revised Draft Guidance for Industry and Investigators; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request." 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 draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Laura Rich or Samantha LohCollado,

Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: AskCTP@fda.hhs.gov.

With regard to the proposed collection of information: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Use of Investigational Tobacco Products." This revised draft guidance replaces the September 2015 draft guidance and, when final, will describe FDA's current thinking regarding the definition of "investigational tobacco product" and discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued and become effective or FDA provides written notice of its intent to change its enforcement policy. It is intended to provide guidance to persons who currently intend to submit study information on tobacco products to FDA as well as to persons who conduct investigations using investigational tobacco products.

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act), enacted on June 22, 2009, amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provided FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

To introduce or deliver for introduction into interstate commerce a new tobacco product, there must be in effect a marketing authorization order issued by FDA for the tobacco product under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j)(c)(1)(A)(i)) unless:

- The manufacturer has submitted a substantial equivalence report for the tobacco product under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) and obtained from FDA a substantial equivalence order under section 910(a)(2)(A)(i) of the FD&C Act;

- The manufacturer has submitted, under 21 CFR 1107.1, a request for an exemption for the tobacco product from the requirement to obtain a substantial equivalence order, FDA has granted the exemption request, and the

manufacturer has made the required submission under section 905(j)(1)(A)(ii) of the FD&C Act and waited 90 days before introducing its product to the market; or

- The manufacturer has submitted a substantial equivalence report in accordance with section 910(a)(2)(B) of the FD&C Act and there is no order finding that the tobacco product is not substantially equivalent.

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

Furthermore, a tobacco product must conform in all respects with applicable tobacco product standards established under section 907 of the FD&C Act (21 U.S.C. 387g). Any tobacco product, including a tobacco product intended for investigational use, is deemed adulterated if it is subject to a tobacco product standard established under section 907 of the FD&C Act and does not in all respects conform with such standard.

Section 910(g) of the FD&C Act gives FDA the authority to issue regulations to exempt tobacco products intended for investigational use from the provisions of chapter IX of the FD&C Act, including premarket submission requirements. FDA intends to propose regulations establishing conditions for exempting investigational tobacco products from certain FD&C Act requirements. Until then, investigational tobacco products are not exempt from applicable FD&C Act requirements, including premarket submission requirements and tobacco product standards.

FDA recognizes that researchers may seek to study tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard. Until regulations governing the use of investigational tobacco products are issued and finalized, FDA intends to evaluate specific uses of investigational tobacco products according to potential human subject protection concerns or other impacts on public health. This revised draft guidance discusses the factors FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products.

FDA issued the September 2015 draft guidance in the **Federal Register** of September 24, 2015 (80 FR 57623). Interested parties were given an opportunity to submit comments by

November 23, 2015. FDA received numerous comments on the September 2015 draft guidance. Based on careful review of these comments, FDA is issuing this revised draft guidance to clarify the Agency's thinking.

II. Significance of Draft Guidance

FDA is issuing this revised draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance replaces the September 2015 draft guidance. The draft guidance, when finalized, will represent the current thinking of FDA regarding the definition of "investigational tobacco product" and discuss the factors FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued or FDA provides written notice of its intent to change its enforcement policy. 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 draft guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry: Use of Investigational Tobacco Products

OMB Control Number 0910-NEW

FDA is announcing the availability of the revised draft guidance entitled "Use of Investigational Tobacco Products." This revised draft guidance supersedes the September 2015 draft guidance and, when final, will describe FDA's current thinking regarding the definition of "investigational tobacco product" and discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations are issued and become effective or FDA provides written notice of its intent to change its enforcement policy. The revised draft guidance is intended to provide guidance to persons who currently intend to submit study information on tobacco products to FDA and to persons who conduct investigations using investigational tobacco products. Such persons may include sponsors, investigators, sponsor-investigators, and contract research organizations (CROs). This revised draft guidance is also intended to provide recommendations to committees or groups formally designated to oversee human subject research (e.g., institutional review boards) involving investigational tobacco products.

FDA recognizes that researchers may seek to study tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard. Until regulations governing the use of investigational tobacco products are issued and finalized, as discussed in the guidance, FDA intends to evaluate specific uses of investigational tobacco products according to potential human subject protection concerns or other impacts on public health.

FDA has identified the following recommendations in the revised draft guidance as collections of information.

In the revised draft guidance, FDA provides examples of information that may help FDA to evaluate specific proposed uses of investigational tobacco products and encourages persons who intend to study investigational tobacco products to meet with FDA to discuss certain topics in connection with investigations. FDA does not recommend that investigators engaging

in nonclinical laboratory investigations correspond with FDA about use of investigational tobacco products in nonclinical studies in all situations. However, sponsors of nonclinical studies may elect to meet with FDA early in the development process to discuss what, if any, animal testing is appropriate and the suitability and acceptability of non-animal tests for a particular tobacco product.

For clinical investigations, FDA encourages sponsors to submit information regarding a proposed use of an investigational tobacco product to FDA for review prior to enrolling subjects in the planned investigation. FDA has created a form entitled "Proposed Use of an Investigational Tobacco Product" to assist sponsors in submitting information. Although use of this form is voluntary, its use will likely reduce the burden hours and will help ensure that sponsors provide complete information for FDA's consideration, processing, and review. The amount of information the revised draft guidance recommends that a sponsor submit depends on the scope of the investigation. For example, the revised draft guidance encourages persons conducting studies with investigational tobacco products that involve minor modifications to legally marketed products to meet with FDA before making a submission. This is because in such cases, it may be appropriate to submit less information. Although the submission of information is voluntary, FDA encourages it, so that sponsors can ensure their investigations account for the factors FDA considers in making enforcement decisions.

Regardless of whether a sponsor intends to consult with FDA in conducting research with an investigational tobacco product, the revised draft guidance contains recommendations for information to include within the study protocol. This information may be considered should FDA assess the enforcement priority of a particular investigation.

Furthermore, to help ensure that studies are conducted in a manner that protects human subjects, the revised draft guidance contains recommendations for procedures sponsors can implement to keep FDA and the committee or group formally designated to oversee research involving human subjects informed about any changes relating to the conduct of, and issues that arise during, the study. In the revised draft guidance, FDA further recommends that the sponsor ensure that clinical investigators maintain complete and accurate records to account for receipt, use, and disposition

of investigational tobacco products. FDA also recommends that the sponsor keep clinical investigators and any committee or group formally designated to oversee research involving human subjects informed of new information on the product, particularly adverse experience information.

In addition, FDA recommends that if there are changes to the current investigational use, sponsors consult with the Office of Science, Center for Tobacco Products (CTP), and any committee or group formally designated to oversee research involving human subjects to ensure that the sponsor's use of an investigational tobacco product continues to appropriately account for the factors FDA intends to consider in determining enforcement priorities. FDA recommends that sponsors also notify FDA if they choose to terminate a study, withdraw or inactivate a protocol, or want to withdraw studies of a product before completion. This information is relevant for FDA to consider in making decisions relating to future investigations involving the tobacco product that was the subject of the terminated study. Moreover, in the revised draft guidance, FDA recommends that under certain circumstances, sponsors also inform any clinical investigators who participated in the discontinued investigation of the reason(s) for discontinuing the clinical investigation.

FDA also makes recommendations related to clinical investigations using investigational tobacco products conducted outside of the United States, but intended for submission to FDA, and refers to section 801(e) of the FD&C Act (21 U.S.C. 381(e)) with respect to exported tobacco products intended for investigational use. The revised draft guidance also recommends that sponsors prepare and maintain certain records and reports for studies conducted outside of the United States but intended for submission to FDA to permit FDA to evaluate the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects.

Finally, in the revised draft guidance, FDA recommends that sponsors, CROs, sponsor-investigators, and clinical investigators maintain documentation to permit evaluation of the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects. The revised draft guidance recommends that records be maintained and available for inspection upon request for a period of at least 4 years after the date on which the investigation

is terminated or completed, or the date that the records are no longer considered necessary for supporting

marketing of a product, or the later of the two dates if both apply.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/FDA form for proposed use of an investigational tobacco product	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital and operating and maintenance costs
Initial Submission	20	1	20	35	700
Protocol Amendments	30	1	30	4	120
Information Amendments	20	1	20	15	300
Administrative Amendments	1	1.5	1.5	0.5 (30 minutes)	0.75
Other Information	3	1	3	0.5 (30 minutes)	1.5
Serious or Unexpected Adverse Experience Reports.	75	3	75	2	150
First year, electronic setup safety reporting portal.	15	1	15	0.5 (30 minutes)	7.5
First year, Electronic Gateway setup and verification certificate (one-time burden).	2	1	2	42 ¹	84	37,800
First year, CTP Portal setup	18	18	3	54
Electronic Gateway Submission (recurring).	2	1	2	3	6	2,700
Total Reporting Burden Hours	1,424	40,500

¹ Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

Table 1 describes the annual reporting burden as a result of respondents submitting information regarding the use of investigational tobacco products in certain clinical investigations. FDA estimates that 20 respondents will submit study information to FDA annually. FDA estimates that it will take each respondent approximately 35 hours to prepare the study information necessary for FDA to issue a response to the proposed use of an investigational tobacco product in these clinical investigations. FDA’s estimate includes the anticipated burden for completing the form for the initial submission, which will include the initial protocol, time for intracompany edits and approvals, as well as the burden for assembling additional information, as described in the revised draft guidance.

Since the initial publication of the September 2015 draft guidance, FDA has updated the estimated burden hours using current information. In addition, FDA has revised table 1 to clarify the types of submissions we anticipate receiving and to clarify what type of information may be included in the initial submission. Specifically, we now estimate that protocol submissions would be included with the initial submission. As such, the approximate burden on respondents is less than discussed in the original Notice of Availability (NOA) for the September 2015 draft guidance.

In response to the original NOA, FDA received one PRA-related comment.

(Comment) The comment stated that FDA has vastly underestimated the time and burden of preparing an initial submission. The comment contended that our estimate is not in line with the Agency’s experience with respect to investigational new drug applications, which the comment also contends is an analogous context.

(Response) FDA does not agree with this comment. The Agency based its estimates on its understanding of the submissions it has received to date. The revised draft guidance announced in this notice also attempts to clarify the Agency’s proposed recommendations regarding submissions.

Following the initial submission, sponsors may wish to provide protocol amendments to reflect certain changes to a protocol. FDA estimates that 30 respondents will submit a protocol amendment. The estimated time for submitting a protocol amendment is 4 hours per response. In addition, FDA estimates that 20 respondents will submit information amendments. Since this may take a little less than half the time of an initial submission, FDA estimates information amendments taking around 15 hours.

FDA estimates that respondents will infrequently need to report administrative amendments. The total number of respondents of this type of information is estimated to be one. FDA estimates administrative amendments taking around 30 minutes per response.

FDA estimates that approximately three respondents will report other

types of submissions. These submissions are estimated to take 30 minutes per response.

FDA estimates that it will receive 75 reports of serious or unexpected adverse experiences. This submission will take an average of 2 hours per report. FDA further estimates that approximately 15 respondents will set up an account in the safety reporting portal for purposes of submitting serious or unexpected adverse experiences. The first year setup of the safety reporting portal for this purpose will take 30 minutes per respondent.

As referenced in the September 2015 draft guidance, FDA allows for three ways of submission. However, FDA strongly encourages the use of electronic format for submission because of its overall efficiency in transmitting information. To submit information through the Electronic Submissions Gateway (ESG), the submitter should first set up an account with WebTrader. FDA estimates from past experience with WebTrader that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the respondent already has an established account in WebTrader for other electronic submissions to FDA, but FDA is assuming that all respondents for these products will be setting up a WebTrader account for the first time in the first year. In subsequent years, the burden hours are estimated at 1 hour to renew the yearly required Verification

Certification. In addition, to submit information through the ESG (or any other means of electronic submission), the submitter must package the information using the eSubmitter formatting software. FDA estimates that the gathering and scanning of information and related correspondence would take approximately 2 hours using the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter process, resulting in 42 hours per response for the first year. For subsequent years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter process, resulting in 3 hours per response each year thereafter.

In addition to the ESG system, an alternative electronic method for respondents to submit electronic

information is through the CTP Portal. Respondents with access to an Industry Account Manager (IAM) may contact the IAM directly for establishment of an account and access to the CTP Portal. Respondents without access to an IAM will be required to identify and establish an IAM. To establish an IAM with the CTP Portal, respondents should contact the CTP Portal Helpdesk and submit required administrative information. FDA estimates that the first-year setup for the CTP Portal is approximately 1 hour per respondent. After receiving access to the CTP Portal, respondents will submit information through the CTP Portal using the eSubmitter system. FDA estimates the gathering, scanning, and submission of information and related correspondence would take approximately 2 hours using the ESG system.

Additionally, there are capital and operating or maintenance costs associated with the ESG platform for the purpose of information collection. The costs are \$30 per year to establish and maintain the ESG verification certificate. The total cost may be lower if the respondents already have a verification certificate for that year for other electronic submissions to FDA. However, for purposes of this estimate, FDA is assuming that all respondents for these products will be incurring this cost. The total costs are estimated to be \$40,500.

The total reporting burden for this collection of information is estimated to be 1,424 hours. These burden estimates were computed using FDA staff expertise and by reviewing comments received from recent FDA information collections for other tobacco-related initiatives.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity records maintained	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records by Sponsors	20	1	20	10	200
Records by Sponsor-Investigators	10	1	10	20	200
Records by Investigators and CROs	15	1	15	15	225
Total Recordkeeping Burden Hours					625

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2 describes the annual recordkeeping burden of maintaining records relating to the investigational use of tobacco products. FDA has updated these numbers based on submissions received since the publication of the September 2015 draft guidance. Compared to FDA's original estimates, the recordkeeping burden has been decreased by 1,025 hours. In addition, FDA has revised table 2 to reflect that we have clarified which

records we are recommending should be maintained. Consequently, FDA now anticipates that 20 sponsors, 10 sponsor-investigators, and 15 investigators and CROs (for a total of 45 respondents) will maintain records relating to the use of investigational tobacco products in clinical investigations. FDA estimates that it will take each sponsor approximately 10 hours per study annually to maintain these records. FDA further estimates that it will take each

sponsor-investigator approximately 20 hours per study annually to maintain these records. Finally, FDA estimates that it will take investigators and CROs approximately 15 hours per study annually to maintain these records. The total reporting burden for recordkeeping is estimated to be 625 hours [200 hours for sponsors (20 × 10) + 200 hours for sponsor-investigators (10 × 20) + 225 for investigators and CROs (15 × 15)].

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Disclosures to Investigators	50	1	50	1	50
Disclosures to any Committee or Group	50	1	50	0.17 (10 minutes) ...	9
Disclosure to Study Subjects	50	2	100	0.5 (30 minutes)	50
Total					109

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3 describes the annual third-party disclosure burden. FDA increased the number of anticipated disclosures based on submissions received since publication

of the September 2015 draft guidance. Additionally, FDA recognizes that sponsors will need to make third-party disclosures to multiple individuals and

groups including investigators, study subjects, as well as any committee or group designated to oversee research. FDA estimates that disclosing

information to investigators will take 1 hour per disclosure. FDA estimates that disclosing information to any committee or group formally designated to oversee research involving human subjects will average 10 minutes per disclosure.

The revised draft guidance also references examples of disclosing information to study subjects such as informed consent. On average, two disclosures per respondent will be provided to study subjects. FDA estimates this will take 30 minutes per disclosure.

The total burden for the collection of information under this revised draft guidance is estimated to be approximately 2,158 hours.

The revised draft guidance also refers to previously approved collections of information. The revised draft guidance includes a recommendation that persons who intend to study tobacco products meet with FDA to discuss research plans. Additional information about how to request meetings with FDA's CTP can be found in FDA's guidance "Meetings with Industry and Investigators on the Research and Development of Tobacco Products" (<https://www.fda.gov/downloads/TobaccoProducts/Labeling/RegulationsGuidance/UCM305282.pdf>).

The collections of information in the guidance referenced have been approved under OMB control number 0910-0731. The collections of information in section 801(e) of the FD&C Act and 21 CFR 1.101(b) have been approved under OMB control number 0910-0482; the collections of information for the Safety Reporting Portal have been approved under OMB control number 0910-0645; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910-0673.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the revised draft guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RegulationsGuidance/default.htm>.

Dated: February 15, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019-02971 Filed 2-20-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Secretary's National Advisory Council on Migrant Health (NACMH) has scheduled a public meeting. Information about NACMH and the agenda for this meeting can be found on the NACMH website at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

DATES: May 22, 2019, 9:00 a.m. to 5:00 p.m. Eastern Time (ET), and May 23, 2019, 9:00 a.m. to 5:00 p.m. ET.

ADDRESSES: The meeting will be held in-person. The address for the meeting is The College at Brockport, State University of New York (SUNY), Cooper Hall, 350 New Campus Drive, Brockport, New York 14420.

FOR FURTHER INFORMATION CONTACT: Esther Paul, Designated Federal Official, (DFO), Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, 16N38B, Rockville, Maryland 20857; (301) 594-4300; or epaul@hrsa.gov.

SUPPLEMENTARY INFORMATION: NACMH provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 217 of Title 42 U.S.C. 218 of the Public Health Service (PHS) Act.

During the May 22-23, 2019, meeting, NACMH will hear presentations from a federal official and experts, and discuss issues facing migrant and seasonal agricultural workers, including the status of agricultural worker health at the local and national levels. Topics addressed at this meeting include health care for aging farmworkers, oral health, and sexual harassment in the agricultural industry. In addition, during the first day of the meeting, on May 22, 2019, the council will hear public comments from migratory and seasonal agricultural workers regarding matters affecting their health. Agenda items are subject to change as priorities dictate. Refer to the NACMH website for any updated information concerning the meeting at <https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/nacmh/index.html>.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to NACMH should be sent to Esther Paul, DFO, using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Esther Paul at the address and phone number listed above at least 10 business days prior to the meeting.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02927 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357-6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857; (301) 443-6593, or visit our website at: <http://www.hrsa.gov/vaccinecompensation/index.html>.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault

compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq.*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that “[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.” Set forth below is a list of petitions received by HRSA on January 1, 2019, through January 31, 2019. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master “shall afford all interested persons an opportunity to submit relevant, written information” relating to the following:

1. The existence of evidence “that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,” and
2. Any allegation in a petition that the petitioner either:

- a. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by” one of the vaccines referred to in the Table, or

- b. “[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine” referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading **FOR FURTHER INFORMATION CONTACT**), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, MD 20857. The Court’s caption (*Petitioner’s Name v. Secretary of Health and Human Services*) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Dated: February 13, 2019.

George Sigounas,
Administrator.

List of Petitions Filed

1. Theresa Collins, Grantsville, West Virginia, Court of Federal Claims No: 19-0001V
2. Cecilia Ortiz, Houston, Texas, Court of Federal Claims No: 19-0002V
3. Sarah K. Jones, Wilmington, North Carolina, Court of Federal Claims No: 19-0003V
4. Tushar Master, Lowell, Massachusetts, Court of Federal Claims No: 19-0006V
5. Paul Christensen, Redmond, Washington, Court of Federal Claims No: 19-0007V
6. Elizabeth Wurdell, Hutchinson, Minnesota, Court of Federal Claims No: 19-0008V
7. Branden Richter, Waupun, Wisconsin, Court of Federal Claims No: 19-0009V
8. Kathryn Keeney, Wesley Chapel, Florida, Court of Federal Claims No: 19-0011V
9. Amy Skopak, Jacksonville, Florida, Court of Federal Claims No: 19-0012V
10. Gary Tucker, Phoenix, Arizona, Court of Federal Claims No: 19-0013V
11. Ann Schnitzer, Melbourne, Florida, Court of Federal Claims No: 19-0015V
12. Lauren Wood, Pittsfield, Massachusetts, Court of Federal Claims No: 19-0016V
13. Anthony Lawler, Brewer, Maine, Court of Federal Claims No: 19-0017V
14. Marie T. Haufler, Evanston, Illinois, Court of Federal Claims No: 19-0018V
15. George Nava, San Antonio, Texas, Court of Federal Claims No: 19-0019V
16. Duane Hutton, Baker City, Oregon, Court of Federal Claims No: 19-0020V
17. Dennis Schmitt, Richardson, Texas, Court of Federal Claims No: 19-0021V
18. Rebecca Smith, Washington, District of Columbia, Court of Federal Claims No: 19-0022V
19. Lesia Jones, Birmingham, Alabama, Court of Federal Claims No: 19-0023V
20. Jolene Snyder, Boone, North Carolina, Court of Federal Claims No: 19-0024V
21. Barry Negri, Howell, New Jersey, Court of Federal Claims No: 19-0028V
22. Mark Zwartz, Chicago, Illinois, Court of Federal Claims No: 19-0029V
23. Matthew Spencer, Washington, District of Columbia, Court of Federal Claims No: 19-0030V
24. Debra L. Sargent, Minneapolis, Minnesota, Court of Federal Claims No: 19-0031V
25. Shirley Tarrant, Greenville, South Carolina, Court of Federal Claims No: 19-0032V
26. Joel Tarantal, Tucson, Arizona, Court of Federal Claims No: 19-0033V
27. Susan TeHennepe, Murfreesboro, Tennessee, Court of Federal Claims No: 19-0034V
28. Linda Wilson, Charleston, South Carolina, Court of Federal Claims No: 19-0035V
29. Saum Eshraghi, Irvine, California, Court of Federal Claims No: 19-0039V
30. Ennis H. Pratcher, Toledo, Ohio, Court of Federal Claims No: 19-0044V
31. Jean Wingard, McMurray, Pennsylvania, Court of Federal Claims No: 19-0045V
32. Susan Martin, San Jose, California, Court of Federal Claims No: 19-0050V
33. Kathleen Schmid, St. Paul, Minnesota, Court of Federal Claims No: 19-0051V
34. Ryan Larsen and Samantha Glover on behalf of D.L., Newburgh, Indiana, Court of Federal Claims No: 19-0056V
35. Javier Colon on behalf of S.C., Rochester, New York, Court of Federal Claims No: 19-0057V
36. Behrooz Mozaffarian, La Mesa, California, Court of Federal Claims No: 19-0060V
37. Leah Polaske, Wellesley Hills, Massachusetts, Court of Federal Claims No: 19-0062V
38. Susan B. Acon on behalf of Agnes Biagini, Deceased, Charleroi, Pennsylvania, Court of Federal Claims No: 19-0064V
39. Kelsey Pomare, Somerville, Massachusetts, Court of Federal Claims No: 19-0065V
40. Heather Geldbach on behalf of Wendy G. Strickland, Deceased, Greensboro, North Carolina, Court of Federal Claims No: 19-0066V
41. William Kritz, Saint Cloud, Florida, Court of Federal Claims No: 19-0068V
42. Jeffrey Barton, Woodland Hills, California, Court of Federal Claims No: 19-0069V
43. Sally Herms, New York, New York, Court

- of Federal Claims No: 19-0070V
44. Andrea Morgan, Glendale, Arizona, Court of Federal Claims No: 19-0071V
 45. John Hendricks, Kirkland, Washington, Court of Federal Claims No: 19-0072V
 46. Irma Carmona, Santa Ana, California, Court of Federal Claims No: 19-0073V
 47. Karena Harrison on behalf of A.N., Jacksonville, Florida, Court of Federal Claims No: 19-0074V
 48. Galia Greenberg, Bethesda, Maryland, Court of Federal Claims No: 19-0075V
 49. Maxine Paul, Dallas, Texas, Court of Federal Claims No: 19-0076V
 50. Valorie Scamyhorn Hodges, Columbus, Ohio, Court of Federal Claims No: 19-0078V
 51. Emily Meacham and Christopher Ryan St. Andre on behalf of Joey Lynn Bates, Deceased, Waynesboro, Tennessee, Court of Federal Claims No: 19-0079V
 52. Tina D'Errico and Paul D'Errico on behalf of R.D., Rockville Center, New York, Court of Federal Claims No: 19-0081V
 53. Wade Hutton, Ironwood, Michigan, Court of Federal Claims No: 19-0082V
 54. Elaine Mercante, Hammond, Louisiana, Court of Federal Claims No: 19-0084V
 55. Hector A. Licon, Jr., San Antonio, Texas, Court of Federal Claims No: 19-0088V
 56. Matthew Doye and Renee Doye on behalf of J.R.D., Carmel, Indiana, Court of Federal Claims No: 19-0089V
 57. Charles Shane Roberson, Evansville, Indiana, Court of Federal Claims No: 19-0090V
 58. Michael Bisceglia and Lori Bisceglia on behalf of N.E.B., North Charleston, South Carolina, Court of Federal Claims No: 19-0091V
 59. Michele Solari, Norwell, Massachusetts, Court of Federal Claims No: 19-0092V
 60. Daniel Ferrari, Joliet, Illinois, Court of Federal Claims No: 19-0093V
 61. Matthew Golitko and Raygan Golitko on behalf of G.M.G., Carmel, Indiana, Court of Federal Claims No: 19-0096V
 62. Lisa Egger, Louisville, Kentucky, Court of Federal Claims No: 19-0098V
 63. Cheryl Kowal, Reading, Pennsylvania, Court of Federal Claims No: 19-0099V
 64. Ana Galan, Kansas City, Missouri, Court of Federal Claims No: 19-0100V
 65. Brian Van Vickle, Forest Lake, Minnesota, Court of Federal Claims No: 19-0101V
 66. Chester Godek, Garden City, New York, Court of Federal Claims No: 19-0106V
 67. Bernaleo Henderson, Sarasota, Florida, Court of Federal Claims No: 19-0107V
 68. Christine Heil, Flint, Michigan, Court of Federal Claims No: 19-0109V
 69. Duane Hoffman, Marion, Ohio, Court of Federal Claims No: 19-0111V
 70. Riley Truttman, Mequon, Wisconsin, Court of Federal Claims No: 19-0112V
 71. Leticia L. Lafosse, White Plains, New York, Court of Federal Claims No: 19-0113V
 72. Laurie Bishara, Parkland, Florida, Court of Federal Claims No: 19-0115V
 73. James D. Daughtery, Richmond, Kentucky, Court of Federal Claims No: 19-0116V
 74. Steven E. Ovenden, Townshend, Vermont, Court of Federal Claims No: 19-0117V
 75. Theresa Marich, East Brunswick, New Jersey, Court of Federal Claims No: 19-0119V
 76. Zahra Aden, Centreville, Virginia, Court of Federal Claims No: 19-0120V
 77. Jane Reininger, San Diego, California, Court of Federal Claims No: 19-0122V
 78. Meghan Kouba, Columbia, Missouri, Court of Federal Claims No: 19-0123V
 79. Andrea Miller, Dallas, Texas, Court of Federal Claims No: 19-0128V
 80. Mamie Porter, Waukegan, Illinois, Court of Federal Claims No: 19-0130V
 81. Rebecca Reske and Timothy Reske on behalf of J.R., Reisterstown, Maryland, Court of Federal Claims No: 19-0131V
 82. Karl Tiedemann, Jr., Port Charlotte, Florida, Court of Federal Claims No: 19-0132V
 83. Sueann Staskewicz, Tabernacle, New Jersey, Court of Federal Claims No: 19-0133V
 84. Kristan McMahan, Clifton Park, New York, Court of Federal Claims No: 19-0134V
 85. Marguerite Bradley, Spring Hill, Florida, Court of Federal Claims No: 19-0135V
 86. Burnell Buckwalter, Florence, South Carolina, Court of Federal Claims No: 19-0136V
 87. Britta Schwartz, Portland, Oregon, Court of Federal Claims No: 19-0137V
 88. Madison Edwards, Lake Charles, Louisiana, Court of Federal Claims No: 19-0138V
 89. Dana Chambers, Phoenix, Arizona, Court of Federal Claims No: 19-0140V
 90. Marsha Goldberg, Cockeysville, Maryland, Court of Federal Claims No: 19-0142V
 91. Sean Farrelly, Portland, Oregon, Court of Federal Claims No: 19-0143V
 92. Cynthia Thomas, Atlanta, Georgia, Court of Federal Claims No: 19-0144V
 93. Rene Reaska, Buffalo, New York, Court of Federal Claims No: 19-0145V
 94. Mohamed Idli, Charlotte, North Carolina, Court of Federal Claims No: 19-0146V
 95. Lisa M. Jackson, Eagan, Minnesota, Court of Federal Claims No: 19-0147V
 96. Kathie M. Hale, Salyersville, Kentucky, Court of Federal Claims No: 19-0154V
 97. Noah Scott Campbell, Dresher, Pennsylvania, Court of Federal Claims No: 19-0156V
 98. Tina McFarlin, San Juan Capistrano, California, Court of Federal Claims No: 19-0157V
 99. Jeffrey Dobyns, Birmingham, Alabama, Court of Federal Claims No: 19-0158V
 100. Barbara Miller, Appleton, Wisconsin, Court of Federal Claims No: 19-0160V
 101. Victor Velazquez, White Plains, New York, Court of Federal Claims No: 19-0162V
 102. Amy J. Johnson on behalf of P.J., Jefferson City, Missouri, Court of Federal Claims No: 19-0163V
 103. David Sazera, Dallas, Texas, Court of Federal Claims No: 19-0164V
 104. Amy Moreno, Riverside, California, Court of Federal Claims No: 19-0170V
 105. Brian Hahn, Cheektowaga, New York, Court of Federal Claims No: 19-0172V
 106. Richard Booth, Amarillo, Texas, Court of Federal Claims No: 19-0174V
 107. Bonnie Locke, Punta Gorda, Florida, Court of Federal Claims No: 19-0175V
 108. Jessica R. Boatwright, Greensboro, North Carolina, Court of Federal Claims No: 19-0176V
 109. Samantha Frost, Phoenix, Maryland, Court of Federal Claims No: 19-0177V
 110. Cynthia McVeigh, Eustis, Florida, Court of Federal Claims No: 19-0178V
 111. Teresa Leon, Yuba City, California, Court of Federal Claims No: 19-0179V
 112. Misty Lotz, Brownsville, Texas, Court of Federal Claims No: 19-0180V
 113. Valerie Eldridge, Little Rock, Arkansas, Court of Federal Claims No: 19-0181V
 114. Michael Kahn, Berlin, New Jersey, Court of Federal Claims No: 19-0182V
 115. Dulce Concepcion Muller-Carillo, Los Angeles, California, Court of Federal Claims No: 19-0183V
 116. Janis Edminster, Placerville, California, Court of Federal Claims No: 19-0184V
 117. Christopher Agard, Victorville, California, Court of Federal Claims No: 19-0185V
 118. Diana Schmauder, Newberg, Oregon, Court of Federal Claims No: 19-0186V

[FR Doc. 2019-02948 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; MCH Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-xxxx-NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. A 60-day **Federal Register** Notice related to this proposed ICR was published in the **Federal Register** on November 16, 2018. No comments were received. OMB will accept comments from the public during the 30-day review and approval period.

DATES: Comments on this ICR should be received no later than March 25, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa

Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Maternal and Child Health (MCH) Jurisdictional Survey Instrument for the Title V MCH Block Grant Program, OMB No. 0906-xxxx-NEW.

Abstract: The purpose of the Title V MCH Block Grant is to improve the health of the nation’s mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/ jurisdiction with needed flexibility to respond to its individual MCH population needs. Unique to the MCH Block Grant is a commitment to performance accountability, while assuring state flexibility. Utilizing a 3-tiered national performance measure framework, which includes National Outcome Measures (NOMs), National Performance Measures (NPMs), and Evidence-Based and Evidence-Informed Strategy Measures, State Title V programs report annually on their performance relative to the selected national performance and outcome measures. Such reporting enables the state and federal program offices to assess the progress achieved in key MCH priority areas and to document Title V program accomplishments.

By legislation (Section 505(a) of Title V of the Social Security Act), the MCH Block Grant Application/Annual Report must be developed by, or in consultation with, the State MCH Health agency. In establishing state reporting requirements, HRSA’s Maternal and Child Health Bureau (MCHB) considers the availability of national data from other federal agencies. Data for the national performance and outcome measures are pre-populated for states in the Title V Information System. National data sources identified for the NPMs and NOMs in the MCH Block Grant program seldom include data from the Title V jurisdictions, with the

exception of the District of Columbia. The eight remaining jurisdictions (American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and U.S. Virgin Islands) have limited access to significant data and MCH indicators, with limited capacity for collecting these data.

Sponsored by HRSA’s MCHB, the MCH Jurisdictional Survey is designed to produce data on the physical and emotional health of mothers and children under 18 years of age in the following eight jurisdictions—American Samoa, Federated States of Micronesia, Guam, Marshall Islands, Northern Mariana Islands, Palau, Puerto Rico, and Virgin Islands. More specifically, the MCH Jurisdictional Survey collects information on factors related to the well-being of children, including health status, visits to health care providers, health care costs, and health insurance coverage. In addition, the MCH Jurisdictional Survey collects information on factors related to the well-being of mothers, including health risk behaviors, health conditions, and preventive health practices. This data collection will enable the jurisdictions to meet federal performance reporting requirements and to demonstrate the impact of Title V funding relative to MCH outcomes for the U.S. jurisdictions in reporting on their unique MCH priority needs.

The MCH Jurisdictional Survey was designed based on information-gathering activities with Title V leadership and program staff in the jurisdictions, experts at the Centers for Disease Control and Prevention, and other organizations with relevant data collection experience. Survey items are based on the National Survey of Children’s Health, the Behavioral Risk Factor Surveillance System, the Youth Behavior Surveillance System, and selected other federal studies. The Survey is designed as a core questionnaire to be administered across all jurisdictions with a supplemental set of survey questions customized to the needs of each jurisdiction.

Need and Proposed Use of the Information: Data from the MCH Jurisdictional Survey will be used to measure progress on national performance and outcome measures under the Title V MCH Block Grant Program. This survey instrument is critical to collecting information on factors related to the well-being of all mothers, children, and their families in the jurisdictional Title V programs, and which address their unique MCH needs.

Likely Respondents: The respondent universe is women age 18 or older who live in one of the eight targeted U.S. jurisdictions (Puerto Rico, U.S. Virgin Islands, Guam, Northern Mariana Islands, American Samoa, Palau, Marshall Islands, or Federated States of Micronesia) and who are mothers or guardians of at least one child aged 0–17 years living in the same household.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden—Hours.

The number of respondents in the table below has decreased slightly for Puerto Rico, U.S. Virgin Islands, and Guam from the numbers included in the 60-day FRN. This decrease is due to a change in the data collection methodology from phone to in-person in these jurisdictions based on the results of the pre-test.

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Burden hours per form	Total burden hours
Adult Parents—Puerto Rico:					
Screeners	810	1	0.03	24.30	204.30
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.07	14.00	
Adult Parents—U.S. Virgin Islands:					
Screeners	903	1	0.03	27.09	207.09
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.07	14.00	
Adult Parents—Guam:					

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Burden hours per form	Total burden hours
Screener	566	1	0.03	16.98	196.98
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.07	14.00	
Adult Parents—American Samoa:					
Screener	395	1	0.03	11.85	187.85
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.05	10.00	
Adult Parents—Federated States of Micronesia:					
Screener	857	1	0.03	25.71	201.71
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.05	10.00	
Adult Parents—Marshall Islands:					
Screener	857	1	0.03	25.71	207.71
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.08	16.00	
Adult Parents—Northern Mariana Islands:					
Screener	600	1	0.03	18.00	200.00
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.08	16.00	
Adult Parents—Palau:					
Screener	967	1	0.03	29.01	199.01
Core	200	1	0.83	166.00	
Jurisdiction Module	200	1	0.02	4.00	
Total	5,955				1,604.65

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02945 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Meeting of the Advisory Committee on Interdisciplinary, Community-Based Linkages

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) has scheduled public meetings for the 2019 calendar year. Information about the ACICBL, agendas, and materials for these meetings can be found on the ACICBL website at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html>.

DATES: May 16, 2019, 8:30 a.m.–5:00 p.m. Eastern Time (ET) and May 17, 2019, 8:30 a.m.–2:00 p.m. ET; and August 14, 2019, 11:00 a.m.–4:00 p.m. ET.

ADDRESSES: The May 16 and May 17, 2019, in-person ACICBL two-day meeting will be held at 5600 Fishers Lane, Rockville, Maryland 20857, and the August 14, 2019, meeting will be held through Adobe Connect webinar. Instructions for joining the meetings either in person or remotely will be posted on the ACICBL website 30 business days before the date of the meeting. For meeting information updates, go to the ACICBL website meeting page at <https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Joan Weiss, Ph.D., RN, CRNP, FAAN, Senior Advisor and Designated Federal Official (DFO), Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301-443-0430; or BHWACICBL@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACICBL provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning activities under sections 750–760, Title VII, Part D of the Public Health Service (PHS) Act.

During the May 2019 and August 2019 meetings, ACICBL members will discuss the overarching topic of population health within the following contexts:

- Inclusion of population health at the nexus of primary health care delivery and public health;

- Use of population health as a method of identifying place based risks, root causes, and possible interventions to address the structural and social determinants of health; and

- Preparation of clinicians to serve as change agents promoting primary prevention by developing the knowledge and skills to address the health needs of populations as measured by a variety of health status indicators.

Agenda items are subject to change as priorities dictate. Refer to the ACICBL website for any updated information concerning the meetings. An agenda will be posted on the website at least 10 business days before the meetings. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACICBL should be sent to Joan Weiss, DFO, using the contact information above at least five business days before the meeting dates.

Individuals who need special assistance or another reasonable accommodation should notify Dr. Weiss at the address and phone number listed above at least 10 business days before the meetings they wish to attend. Since all in-person meeting will occur in a federal government building, attendees

must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019-02928 Filed 2-20-19; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2019-0038]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0039

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0039, Declaration of Inspection Before Transfer of Liquid Cargo in Bulk, without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 22, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2019-0038] to the Coast Guard 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.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King, Jr., Ave. SE, STOP 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information

Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2019-0038], and must be received by April 22, 2019.

Submitting Comments

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. Documents mentioned in this notice, and all public comments, are 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.

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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Declaration of Inspection Before Transfer of Liquid Cargo in Bulk.

OMB Control Number: 1625-0039.

Summary: A Declaration of Inspection (DOI) documents the transfer of oil and hazardous materials, to help prevent spills and damage to a facility or vessel. Persons-in-charge of the transfer operations must review and certify compliance with procedures specified by the terms of the DOI.

Need: Title 33 U.S.C. 1321(j) authorizes the Coast Guard to establish regulations to prevent the discharge of oil and hazardous material from vessels and facilities. The DOI regulations appear at 33 CFR 156.150 and 46 CFR 35.35-30.

Forms: None.

Respondents: Persons-in-charge of transfers.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has increased from 77,973 hours to 80,051 hours a year due to an increase in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: February 7, 2019.

James D. Roppel,

U.S. Coast Guard, Chief, Office of Information Management.

[FR Doc. 2019-02921 Filed 2-20-19; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2018-0498]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625-0071

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to

the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0071, Boat Owner's Report; Possible Safety Defect, without change. Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before April 22, 2019.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG-2018-0498] to the Coast Guard 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.

A copy of the ICR is available through the docket on the internet at <http://www.regulations.gov>. Additionally, copies are available from: Commandant (CG-612), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King, Jr., Ave. SE, STOP 7710, Washington, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: Mr. Anthony Smith, Office of Information Management, telephone 202-475-3532, or fax 202-372-8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of

the Collection on respondents, including the use of automated collection techniques or other forms of information technology. In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG-2018-0498], and must be received by April 22, 2019.

Submitting Comments

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. Documents mentioned in this notice, and all public comments, are 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.

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, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Information Collection Request

Title: Boat Owner's Report, Possible Safety Defect.

OMB Control Number: 1625-0071.

Summary: The collection of information provides a means for consumers who believe their recreational boats or designated associated equipment contain substantial risk defects or fail to comply with Federal safety standards to report the deficiencies to the Coast Guard for investigation and possible remedy.

Need: Title 46 U.S.C. 4310 gives the Coast Guard the authority to require manufacturers of recreational boats and certain items of designated associated equipment to notify owners and remedy: (1) Defects that create a substantial risk of personal injury to the public; and (2) failures to comply with applicable Federal safety standards.

Forms: CG-5578, Boat Owner's Report—Possible Safety Defect.

Respondents: Owners and users of recreational boats and items of designated associated equipment.

Frequency: One time.

Hour Burden Estimate: The estimated burden has decreased from 18 hours to 12 hours a year due to a decrease in the estimated annual number of respondents.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended.

Dated: February 7, 2019.

James D. Roppel,

U.S. Coast Guard, Chief, Office of Information Management.

[FR Doc. 2019-02918 Filed 2-20-19; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0102]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Freedom of Information/Privacy Act Request

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 25, 2019.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at dhsdeskofficer@omb.eop.gov. All submissions received must include the agency name and the OMB Control Number 1615-0102 in the subject line.

You may wish to consider limiting the amount of personal information that you

provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommès, Chief, 20 Massachusetts Avenue NW, Washington, DC 20529-2140, Telephone number (202) 272-8377 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at (800) 375-5283; TTY (800) 767-1833.

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on December 11, 2018, at 83 FR 63665, allowing for a 60-day public comment period. USCIS did receive two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at <http://www.regulations.gov> and enter USCIS-2008-0028 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Freedom of Information/Privacy Act Request.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* G-639; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. Form G-639 and the Freedom of Information Act Immigration Records System (FIRST) e-filing process are provided as a convenient means for individuals to provide data necessary for identification of a particular record being requested under the Freedom of Information/Privacy Act (FOIA/PA).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection Form G-639 is 165,818 and the estimated hour burden per response is .67 hours; the estimated total number of respondents for the information collection FIRST (e-filing) is 41,455 and the estimated hour burden per response is .5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 131,825 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is \$2,445,821.

Dated: February 15, 2019.

Jerry L. Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2019-02997 Filed 2-20-19; 8:45 am]

BILLING CODE 9111-97-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R5-ES-2018-0091;
FXES11120500000-189-FF05E00000]

Amended Habitat Conservation Plan, Application for an Incidental Take Permit for Piping Plover, Massachusetts Division of Fisheries and Wildlife; Draft Finding of No Significant Impact

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability of documents; request for public comment.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce receipt of an application from the Massachusetts Division of Fisheries and Wildlife (MADFW) to amend its Habitat Conservation Plan For Piping Plover for unavoidable take of the federally listed threatened Atlantic Coast piping plover incidental to otherwise lawful activities, specifically recreational activities and beach operations on piping plover breeding beaches in Massachusetts. We are making available the draft amendment, MADFW's application, and our draft Finding of No Significant Impact under the National Environmental Policy Act that evaluates the impacts on the human environment associated with the proposed amendment. We provide this notice to seek comments from the public and Federal, Tribal, State, and local governments.

DATES: We will accept comments until March 25, 2019. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**) must be received by 11:59 p.m. Eastern Standard Time on the closing date.

ADDRESSES: You may submit written comments by one of the following methods:

Electronically: Go to the Federal eRulemaking Portal website at <http://www.regulations.gov>. In the Search box, enter FWS-R5-ES-2018-0091, which is the docket number for this notice. Click on the appropriate link to locate this document and submit a comment.

By hard copy: Submit by U.S. mail or hand-delivery to Public Comments Processing, Attn: Docket No. FWS-R5-ES-2018-0091; Division of Policy, Performance and Management Programs; U.S. Fish and Wildlife Service; 5275 Leesburg Pike, ABHC-PPM; Falls Church, VA 22041-3803.

We request that you send comments by only one of the methods described above. We will post all information

received on <http://www.regulations.gov>. This generally means that we will post any personal information you provide us (see the Public Comments section for more information).

FOR FURTHER INFORMATION CONTACT:

Thomas Chapman, by mail at U.S. Fish and Wildlife Service, New England Field Office, 70 Commercial Street, Suite 300, Concord, NH 03301; by phone at 603-223-2541; or via the Federal Relay Service at 800-877-8339.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce receipt of an application from the Massachusetts Division of Fisheries and Wildlife (MADFW) to amend its Habitat Conservation Plan For Piping Plover (HCP) for unavoidable take of the federally listed threatened Atlantic Coast piping plover (*Charadrius melodus*) incidental to otherwise lawful activities, specifically recreational activities and beach operations on piping plover breeding beaches in Massachusetts, and the associated permit that the Service approved on July 8, 2016. The proposed amendment would facilitate HCP implementation by addressing unusual circumstances where a limited number of sites need additional management flexibility.

The Service is making available the draft amendment and the MADFW's application. Through this notice we also announce the availability of a draft Finding of No Significant Impact (FONSI) under the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) that evaluates the impacts on the human environment associated with the proposed amendment. We provide this notice to seek comments from the public and Federal, Tribal, State, and local governments.

We received an application from the MADFW for an amendment to the HCP and ITP (Incidental Take Permit; Federal Fish and Wildlife Permit number TE01281C-0) to increase the site-specific allowable exposure to take of piping plover pairs from certain covered activities at a limited number of sites in limited circumstances. The Service's proposed action is issuing an amended ITP in response to the MADFW's proposed changes to how it intends to allocate site-specific exposure of piping plovers to take.

The 2016 HCP generally limits site-specific take exposure to 15 percent of breeding pairs except that the MADFW may allow take exposure of 30 percent of breeding pairs at up to five sites; sites with fewer than seven pairs are allowed take exposure of one breeding pair. The amendment would deal only with the

exception to the general take exposure limit of 15 percent, increasing the maximum exposure to 75 percent at eight sites statewide. The deviation in maximum exposure would occur only in association with "Use of Roads and Parking Lots in the Vicinity of Unfledged Chicks" and "Oversand Vehicle (OSV) Use in the Vicinity of Unfledged Chicks." Under the amended HCP, the general maximum allowable take exposure would remain at 15 percent for all covered activities; however, at up to eight sites, the MADFW could allow take exposure of up to 75 percent of breeding pairs, including at sites with fewer than seven pairs, from the two covered activities mentioned above. The proposed action would not (1) increase the statewide take level authorized under the ITP; (2) change the covered species, covered activities, or conservation strategy including required mitigation; or (3) extend the ITP duration.

Under NEPA, this notice advises the public that we have gathered the information necessary to determine whether and how the draft amendment to the HCP under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA), may impact the human environment, and whether supplementation of the EA is warranted.

Availability of Documents

You may obtain copies of the proposed amendment to the HCP and draft FONSI on the internet at the New England Field Office's website at <https://www.fws.gov/newengland/> or at <https://www.regulations.gov> at Docket No. FWS-R5-ES-2018-0091. Copies of the proposed HCP amendment and draft FONSI also can be made available for public review during regular business hours at the New England Field Office, 70 Commercial Street, Suite 300, Concord, NH 03301. Those who do not have access to the internet or cannot visit our office can request copies by telephone at 603-223-2541, or by letter to the New England Field Office.

Background

The 2016 ITP issued to the MADFW authorized take caused by recreational activities and beach operations that deviate from State and Federal guidelines for avoiding take (*Guidelines for Managing Recreational Use of Beaches to Protect Piping Plovers, Terns and Their Habitats in Massachusetts* (MADFW 1993; <http://www.mass.gov/eea/docs/dfg/nhsp/species-and-conservation/ma-shorebird-management-guidelines.pdf>, accessed March 20, 2018); *Guidelines for Managing Recreational Activities In*

Piping Plover Breeding Habitat On The U.S. Atlantic Coast To Avoid Take Under Section 9 Of The Endangered Species Act (USFWS 1994; <http://www.fws.gov/northeast/pipingplover/pdf/recguide.pdf>, accessed March 20, 2018)). The HCP functions as an umbrella plan to allow the MADFW to extend incidental take coverage via Certificates of Inclusion (COI) to approved landowners and beach managers to implement a suite of covered activities if they meet the eligibility and COI application requirements described in the HCP. The MADFW, as the permit holder, manages and implements the statewide conservation program outlined in the HCP to minimize and mitigate for the impacts of the incidental take. The MADFW is also responsible for administering the Massachusetts Endangered Species Act and its implementing regulations (MESA; MGL c. 131A; 321 CMR 10.00) and issues separate MESA conservation and management permits for piping plovers and other State-listed species that may be impacted by the implementation of the HCP's covered activities.

The proposed amendment would facilitate implementation of the HCP and address limited circumstances where there is a need to exceed the current maximum allowable take exposure of 30 percent at five sites statewide. Again, this is an exception to the general limit of 15 percent that would apply elsewhere. As currently written, the exception to site-specific take exposure limit of the 2016 HCP creates an obstacle to a few beach operators who might otherwise benefit from participating in the HCP. For small beaches, multiple pairs of plovers nesting at critical access points could preclude all access if take exposure is restricted to 30 percent or less, because sites with three to seven pairs of piping plovers are currently limited to take exposure of one to two plover nests, broods, or territories. Beaches with roads and parking lots adjacent to piping plover breeding habitat may experience occasions when the majority of the pairs congregate their nests or young at critical recreational access points resulting in the total closure of parking lots or improved roads. The proposed action would increase the maximum allowable take exposure from 30 percent of the breeding pairs at up to five sites to 75 percent of breeding pairs at up to eight sites, statewide.

The proposed amendment is largely an administrative change, because it would not change how the HCP is implemented, but would only alter MADFW's flexibility in allocating the

annual statewide take exposure. The amendment would not affect the 2016 HCP's sliding scale method for determining the annual allowable take of broods, nests, or territories based on the 3-year running statewide population average. In addition, the amendment would apply to only two covered activities: "Use of Roads and Parking Lots in the Vicinity of Unfledged Chicks" and "OSV Use in the Vicinity of Unfledged Chicks." It would not apply to "Recreation Management and Beach Operations." Additionally, the proposed amendment would not alter limits on the habitat, broods, or pairs affected through reduced proactive fencing, reduced buffers around nests, or nest moving.

The FONSI anticipates some site-specific impacts to piping plovers as a result of the increase in allowable take exposure and associated decrease in productivity at up to eight sites. However, the FONSI anticipates that the impacts to the piping plover and the human environment statewide will be essentially the same as those previously analyzed in our 2016 Environmental Assessment (EA), because at a full allocation of authorized take, for any increase in breeding pairs exposed to take at one site, the MADFW would have to make a corresponding reduction in the remaining number of pairs that could be exposed to take at other sites. Moreover, the nature of the activities being conducted has not changed.

National Environmental Policy Act

When we issued the initial permit to the MADFW, we thoroughly analyzed the associated impacts to the human environment in our EA, concluding our NEPA analysis with a Finding of No Significant Impacts. We prepared a draft FONSI on the proposed action and have made it available for public inspection (see Availability of Documents). In it, we tentatively determine that the proposed action would not cause significant impacts on the human environment and that supplementation of the EA is not warranted. We base that preliminary conclusion on: The limited nature of the proposed amendment that the deviation from the maximum exposure limit at a site would apply in a minority of situations; the manner in which the activities will be conducted has not been altered; and, the overall take allocation remains unchanged.

Public Comments

The Service invites the public to comment on the proposed HCP amendment and draft FONSI during a 30-day public comment period (see **DATES**). You may submit comments by

one of the methods shown under **ADDRESSES**.

Public Availability of Comments

We will post all public comments and information received electronically or via hard copy on our website at <https://regulations.gov>. All comments received, including names and addresses, will become part of the administrative record and will be available to the public. 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 request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Authority

This notice is provided pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Dated: February 14, 2019.

Paul Phifer,

Assistant Regional Director, Ecological Services, Northeast Region.

[FR Doc. 2019-02939 Filed 2-20-19; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R4-ES-2018-N139; FXES11140400 000-189-FF04E00000]

Endangered Species; Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation or survival of endangered species under the Endangered Species Act of 1973, as amended. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will take into consideration any information that we

receive during the public comment period.

DATES: We must receive written data or comments on the applications by March 25, 2019.

ADDRESSES: Reviewing Documents: Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act. Submit a request for a copy of such documents to Karen Marlowe (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Comments: If you wish to comment, you may submit comments by one of the following methods:

- **U.S. mail or hand-delivery:** U.S. Fish and Wildlife Service Regional Office, Ecological Services, 1875 Century Boulevard, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).

- **Email:** permitsR4ES@fws.gov. Please include your name and return address in your email message. If you do not receive a confirmation from the U.S. Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed in **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, Permit Coordinator, 404-679-7097 (telephone), karen_marlowe@fws.gov (email), or 404-679-7081 (fax). Individuals who are hearing or speech impaired may call the Federal Relay Service at 1-800-877-8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We invite review and comment from local, State, and Federal agencies and the public on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activities. The ESA's definition of "take" includes hunting, shooting, harming, wounding, or killing, and also such activities as pursuing, harassing, trapping, capturing, or collecting.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and

collection. Our regulations implementing section 10(a)(1)(A) for these permits are found at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and

enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

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.

Permit application No.	Applicant	Species/numbers	Location	Activity	Type of take	Permit action
TE 21570C-1	Tennessee Wildlife Resources Agency, Nashville, TN.	Alabama cavefish (<i>Speoplatyrhinus poulsoni</i>), Laurel Dace (<i>Chrosomus saylori</i>), Bluemask darter (<i>Etheostoma akatulo</i>), Boulder darter (<i>Etheostoma wapiti</i>), Cherokee darter (<i>Etheostoma scotti</i>), Cumberland darter (<i>Etheostoma susanae</i>), Diamond darter (<i>Crystallaria cincotta</i>), Duskytail darter (<i>Etheostoma percnum</i>), Etowah darter (<i>Etheostoma etowahae</i>), Fountain darter (<i>Etheostoma fonticola</i>), Kentucky arrow darter (<i>Etheostoma spilotum</i>), Okaloosa darter (<i>Etheostoma okaloosae</i>), Pearl darter (<i>Percina aurora</i>), Relict darter (<i>Etheostoma chienense</i>), Rush darter (<i>Etheostoma phytophilum</i>), Vermilion darter (<i>Etheostoma chermocki</i>), Watercress darter (<i>Etheostoma nuchale</i>), Yellowcheek darter (<i>Etheostoma moorei</i>), Conasauga logperch (<i>Percina jenkinsi</i>), Roanoke logperch (<i>Percina rex</i>), Chucky madtom (<i>Noturus crypticus</i>), Pygmy madtom (<i>Noturus stanauli</i>), Scioto madtom (<i>Noturus trautmani</i>), Smoky madtom (<i>Noturus baileyi</i>), Cahaba shiner (<i>Notropis cahabae</i>), Palezone shiner (<i>Notropis albizonatus</i>), Alabama sturgeon (<i>Scaphirhynchus suttkusi</i>), Pallid sturgeon (<i>Scaphirhynchus albus</i>), White sturgeon (<i>Acipenser transmontanus</i>), and Spring pygmy sunfish (<i>Elassoma alabamae</i>).	Tennessee	Captive propagation and release.	Collect, transport, hold in captivity for more than 45 consecutive days, release.	Amendment.
TE 94849B-1	Copperhead Environmental Consulting, Paint Lick, KY.	Indiana bat (<i>Myotis sodalis</i>)	Alabama	Determine pregnancy timing.	Collect blood samples	Amendment.
TE 02332D-0	Michelle Gilley, Mars Hill, NC.	Gray bats (<i>Myotis grisescens</i>), Indiana bats (<i>Myotis sodalis</i>), Northern long-eared bats (<i>Myotis septentrionalis</i>), Virginia big-eared bats (<i>Corynorhinus townsendii virginianus</i>), and Carolina northern flying squirrel (<i>Glaucomys sabrinus coloratus</i>).	Bats: Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. Carolina northern flying squirrel: North Carolina, Tennessee, and Virginia.	Presence/absence surveys, population monitoring, and studies to document habitat use.	Bats: Capture with mist nets and harp traps, handle, identify, band, radio-tag, collect hair samples, and wing-punch. Carolina northern flying squirrel: Capture in nest boxes or live traps, handle, radio-tag, collect hair samples, and ear tag.	New.
TE 05528D-0	John Manuel, Asheville, NC.	Gray bats (<i>Myotis grisescens</i>), Indiana bats (<i>Myotis sodalis</i>), and Northern long-eared bats (<i>Myotis septentrionalis</i>).	Alabama, Arkansas, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/absence surveys, habitat assessments, population dynamics evaluations, and migration research.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio-tag, collect hair samples, wing-punch, and swab.	New.

Permit application No.	Applicant	Species/numbers	Location	Activity	Type of take	Permit action
TE 95412A-0	Kentucky Division of Water, Frankfort, KY.	Big Sandy crayfish (<i>Cambarus callainus</i>), Blackside dace (<i>Chrosomus cumberlandensis</i>), Cumberland darter (<i>Etheostoma susanae</i>), Duskytail darter (<i>Etheostoma percnurum</i>), Kentucky arrow darter (<i>Etheostoma spilotum</i>), Palezone shiner (<i>Notropis albizonatus</i>), Relict darter (<i>Etheostoma chienense</i>), Clubshell (<i>Pleurobema clava</i>), Cumberland bean (<i>Villosa trabalis</i>), Cumberland combshell (<i>Epioblasma brevidens</i>), Cumberland elktoe (<i>Alasmidonta atropurpurea</i>), Dromedary pearlymussel (<i>Dromus dromas</i>), Fanshell (<i>Cyprogenia stegaria</i>), Fat pocketbook (<i>Potamilus capax</i>), Fluted kidneyshell (<i>Ptychobranchus subtentum</i>), Littlewing pearlymussel (<i>Pegias fabula</i>), Northern riffleshell (<i>Epioblasma torulosa rangiana</i>), Orangefoot pimpleback (<i>Plethobasus cooperianus</i>), Oyster mussel (<i>Epioblasma capsaeformis</i>), Pink mucket (<i>Lampsilis abrupta</i>), Purple cat's paw (<i>Epioblasma obliquata obliquata</i>), Rabbitsfoot (<i>Quadrula cylindrica cylindrica</i>), Rayed bean (<i>Villosa fabalis</i>), Ring pink (<i>Obovaria retusa</i>), Rough pigtoe (<i>Pleurobema plenum</i>), Scaleshell mussel (<i>Leptodea leptodon</i>), Sheepnose mussel (<i>Plethobasus cyphus</i>), Slabside pearlymussel (<i>Pleuonaia dolabelloides</i>), Snuffbox mussel (<i>Epioblasma triquetra</i>), Spectaclecase (<i>Cumberlandia monodonta</i>), and Tan riffleshell (<i>Epioblasma florentina walkeri</i> (=E. walkeri)).	Kentucky	Presence/absence surveys.	Collect, handle, and release.	New.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Franklin Arnold,

Acting Assistant Regional Director, Ecological Services, Southeast Region.

[FR Doc. 2019-02914 Filed 2-20-19; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[190A2100DD/AAKC001030/A0A501010.999900 253G]

Notice of Deadline for Submitting Completed Applications To Begin Participation in the Tribal Self-Governance Program in Fiscal Year 2020 or Calendar Year 2020

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of application deadline.

SUMMARY: In this notice, the Office of Self-Governance (OSG) establishes a March 1, 2019 deadline for Indian Tribes/consortia to submit completed applications to begin participation in

the Tribal self-governance program in fiscal year 2020 or calendar year 2020.

DATES: Completed application packages must be received by the Director, Office of Self-Governance, by March 1, 2019.

ADDRESSES: Application packages for inclusion in the applicant pool should be sent to Ms. Sharee M. Freeman, Director, Office of Self-Governance, Department of the Interior, Mail Stop 2071-MIB, 1849 C Street NW, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Dr. Kenneth D. Reinfeld, Office of Self-Governance, Telephone (703) 390-6551.

SUPPLEMENTARY INFORMATION: Under the Tribal Self-Governance Act of 1994 (Pub. L. 103-413), as amended by the Fiscal Year 1997 Omnibus Appropriations Bill (Pub. L. 104-208), and section 1000.15(a) of Title 25 of the Code of Federal Regulations, the Director, Office of Self-Governance may select up to 50 additional participating Tribes/consortia per year for the Tribal self-governance program and negotiate and enter into a written funding agreement with each participating Tribe. The Act mandates that the Secretary of the Interior submit copies of the funding agreements at least 90 days before the proposed effective date to the appropriate committees of the Congress and to each Tribe that is served by the

Bureau of Indian Affairs' agency that is serving the Tribe that is a party to the funding agreement. Initial negotiations with a Tribe/consortium located in a region and/or agency which has not previously been involved with self-governance negotiations will take approximately 2 months from start to finish. Agreements for an October 1 to September 30 funding year need to be signed and submitted by July 1. Agreements for a January 1 to December 31 funding year need to be signed and submitted by October 1.

Purpose of Notice

The regulations at 25 CFR 1000.10 to 1000.31 will be used to govern the application and selection process for Tribes/consortia to begin their participation in the Tribal self-governance program in fiscal year 2020 and calendar year 2020. Applicants should be guided by the requirements in these subparts in preparing their applications. Copies of these subparts may be obtained from the information contact person identified in this notice.

Tribes/consortia wishing to be considered for participation in the Tribal self-governance program in fiscal year 2020 or calendar year 2020 must respond to this notice, except for those Tribes/consortia which are: (1) Currently involved in negotiations with

the Department; or (2) one of the 128 Tribal entities with signed agreements.

Information Collection

This information collection is authorized by OMB Control Number 1076-0143, Tribal Self-Governance Program, which expires March 31, 2019.

Dated: December 20, 2018.

Tara Sweeney,

Assistant Secretary, Indian Affairs.

[FR Doc. 2019-02860 Filed 2-20-19; 8:45 am]

BILLING CODE 4337-15-P

INTERNATIONAL TRADE COMMISSION

[USITC SE-19-002]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: February 26, 2019 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW, Washington, DC 20436, Telephone: (202) 205-2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote on Inv. Nos. 701-TA-592 and 731-TA-1400 (Final) (Plastic Decorative Ribbon from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission by March 11, 2019.

5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting. Earlier announcement of this meeting was not possible.

By order of the Commission.

Issued: February 13, 2019.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2019-03065 Filed 2-19-19; 11:15 am]

BILLING CODE 7020-02-P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140-0095]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Office of Human Resources and Professional Development Student and Supervisor Training Validation Surveys

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 1140-0095 (Office of Human Resources and Professional Development Student and Supervisor Training Validation Surveys) is being revised due to a change in burden, since there is a reduction in both the total responses and total burden hours due to less respondents.

DATES: Comments are encouraged and will be accepted for 60 days until April 22, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Scott either by mail at ATF Human Resources and Professional Development, 99 New York Ave. NE, Washington, DC 20226, by email at james.scott@atf.gov, or by telephone at 202-648-8385.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

- including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision a currently approved collection.
2. *The Title of the Form/Collection:* Office of Human Resources and Professional Development Student and Supervisor Training Validation Surveys.
3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*
Form number (if applicable): None.
Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.
4. *Affected public who will be asked or required to respond, as well as a brief abstract:*
Primary: State, Local and Tribal Government.
Other (if applicable): None.
Abstract: The surveys are sent to students and their supervisors 6 months after completing training to determine if the training adequately prepared them for duties as an explosives detection canine handler. Survey responses are used to improve the training and ensure it remains current to the needs of the field. The surveys are used for both the basic explosives canine handler-training program and the advanced EDC SEEK K-9 courses.
5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50 respondents will utilize either of the two the surveys and it will take each respondent approximately 15 minutes to complete one of the surveys.
6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 12.5 (13 hours) which is equal to 50 (# of respondents) * 1 (# of responses per respondents) * .25 (15 minutes).
7. *An Explanation of the Change in Estimates:* The adjustments associated with this collection include a reduction in the total respondents and burden

hours by 50 and 12.5 (13) hours respectively, since the previous renewal in 2016.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-02936 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140-0066]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Manufacturers of Ammunition, Records and Supporting Data of Ammunition Manufactured and Disposed of

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed collection OMB 1140-0066 (Manufacturers of Ammunition, Records and Supporting Data of Ammunition Manufactured and Disposed of) is being revised due to a change in burden, since there is an increase in the number of responses to this information collection, which has also caused an increase in the total collection burden hours.

DATES: Comments are encouraged and will be accepted for 60 days until April 22, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact:

Jason Gluck, ATF Firearms Industry Programs Branch, either by mail at 99 New York Ave. NE, Washington, DC 20226, by email at *Fipb-informationcollection@atf.gov*, or by telephone at 202-648-7190.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Manufacturers of Ammunition, Records and Supporting Data of Ammunition Manufactured and Disposed of.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other (if applicable): None.

Abstract: The manufacturer's records are used by ATF in criminal investigations and compliance inspections, to fulfill the Bureau's mission to enforce the Gun Control Law.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* About half of an estimated 376

respondents may utilize this information collection to provide a total 188 responses, and it will take each respondent 2 minutes to provide their response.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 6.2 (6) hours, which is equal to 376 (total # of respondents) * .5 (total # of responses per respondents) * .033 (2 minutes).

7. *An Explanation of the Change in Estimates:* The changes in burden are due to an increase in the number of responses to this collection from 159 during the last renewal in 2016, to 188 currently. Consequently, the burden hours for this information collection has also increased slightly from 5 to 6.2 (6) hours respectively.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-02935 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

Antitrust Division

United States, et al. v. CVS Health Corporation and Aetna Inc.; Response to Public Comments

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)-(h), the United States hereby publishes below the Response to Public Comments on the Proposed Final Judgment in *United States, et al. v. CVS Health Corporation and Aetna Inc.*, Civil Action No. 1:18-cv-02340, which was filed in the United States District Court for the District of Columbia on February 13, 2019, together with copies of the 173 comments received by the United States.

Pursuant to the Court's February 9, 2019 order, comments were published electronically and are available to be viewed and downloaded at the Antitrust Division's Web site, at: <https://www.justice.gov/atr/us-v-cvs-health-corp-and-aetna-inc-index-comments>. A copy of the United States' response to the comments is also available at the same location. Copies of the comments

and the United States’ response are available for inspection at the Office of the Clerk of the United States District Court for the District of Columbia. Copies of these materials may also be obtained from the Antitrust Division upon request and payment of the

copying fee set by Department of Justice regulations.

Patricia A. Brink,
Director of Civil Enforcement.

United States District Court for the District of Columbia

United States of America et al., Plaintiffs,
v. CVS Health Corporation and AETNA Inc.,
Defendants.

Case No. 1:18–cv–02340–RJL

RESPONSE OF PLAINTIFF UNITED STATES TO PUBLIC COMMENTS ON THE PROPOSED FINAL JUDGMENT

TABLE OF CONTENTS

I. Introduction 1
 II. Procedural History 2
 III. Standard of Judicial Review 2
 IV. The Investigation, the Harm Alleged in the Complaint, and the Proposed Final Judgment 8
 V. Summary of Public Comments and the United States’ Response 12
 A. Comments Regarding WellCare’s Suitability as a Divestiture Buyer and Ability to Compete Effectively 13
 1. WellCare is an experienced and effective competitor 13
 2. WellCare is an independent competitor to CVS 17
 3. Prior health insurance merger remedies do not cast doubt on the divestiture 19
 4. The remedy does not create new structural concerns in the markets for individual PDPs 21
 5. The licensing provisions related to the Aetna brand protect WellCare’s ability to compete using the divested assets 23
 6. The sales price does not cast doubt on WellCare’s intention to compete 23
 B. Comments Related to the Vertical Aspects of CVS’s Acquisition of Aetna 24
 1. Input foreclosure is unlikely to occur and is beyond the scope of the Complaint 26
 2. Customer foreclosure is unlikely to occur and is beyond the scope of the Complaint 27
 3. Vertical concerns are not addressable under the Tunney Act’s standard of review 29
 C. Other Miscellaneous Comments 30
 D. Comments in Support of the Merger 34
 VI. Conclusion 35

I. Introduction

As required by the Antitrust Procedures and Penalties Act (the “APPA” or “Tunney Act”), 15 U.S.C. §§ 16(b)–(h), the United States hereby responds to the public comments received about the proposed Final Judgment in this case. After careful consideration of the comments, the United States continues to believe that the proposed remedy will address the harm alleged in the Complaint and is therefore in the public interest.

The remedy preserves competition for the approximately 21 million beneficiaries who purchase individual prescription drug plans (“individual PDPs”) in the United States. The remedy fully addresses the competitive threat posed by the merger by requiring CVS to divest Aetna’s nationwide individual PDP business to WellCare Health Plans, Inc., an experienced health insurer focused on government-sponsored health plans, including individual PDPs. By requiring a nationwide divestiture, the remedy provides WellCare with the assets and scale necessary to maintain competition in the 16 regions identified in the Complaint. The remedy also provides WellCare with access to all of the records, employees, and other rights necessary to ensure that WellCare can step into Aetna’s shoes. The remedy thus preserves the competition that

otherwise would be lost through the merger and ensures that WellCare will effectively replace Aetna as an independent and vigorous competitor.

The United States received 173 comments about the proposed remedy reflecting a wide range of views. Some comments supported the merger. Other comments acknowledged the significant scope of the divestiture, but expressed concerns about the divestiture buyer. Many comments raised issues that are outside the scope of the Tunney Act review. After careful consideration of these comments, the United States maintains that the remedy in the proposed Final Judgment provides comprehensive relief that satisfies the Tunney Act’s public-interest standard.

The United States will publish the comments and this response on the Antitrust Division’s website and is submitting to the *Federal Register* this response and the website address at which the comments may be viewed and downloaded, as authorized by the Court’s order dated February 9, 2019. Following *Federal Register* publication, the United States will move the Court to enter the proposed Final Judgment.

II. Procedural History

On December 3, 2017, CVS entered into an agreement to acquire Aetna in a merger valued at approximately \$69 billion. On October 10, 2018, the United

States filed a civil antitrust Complaint seeking to enjoin CVS from acquiring Aetna because the proposed acquisition would substantially lessen competition for the sale of individual PDPs in 16 regions in the United States in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

Simultaneously with the filing of the Complaint, the United States filed a proposed Final Judgment, a Stipulation signed by the parties that consents to entry of the proposed Final Judgment after compliance with the requirements of the Tunney Act, and a Competitive Impact Statement describing the transaction and the proposed Final Judgment. The United States caused the Complaint, the proposed Final Judgment, and Competitive Impact Statement to be published in the *Federal Register* on October 17, 2018, *see* 83 Fed. Reg. 52558 (October 17, 2018), and caused notice regarding the same, together with directions for the submission of written comments relating to the proposed Final Judgment, to be published in *The Washington Post* on October 12–18, 2018. The 60-day period for public comment ended on December 17, 2018.

III. Standard of Judicial Review

The Clayton Act, as amended by the APPA, requires that proposed consent judgments in antitrust cases brought by

the United States be subject to a 60-day comment period, after which the court shall determine whether entry of the proposed Final Judgment “is in the public interest.” 15 U.S.C. § 16(e)(1). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. § 16(e)(1)(A) & (B). In considering these statutory factors, the court’s inquiry is necessarily a limited one as the government is entitled to “broad discretion to settle with the defendant within the reaches of the public interest.” *United States v. Microsoft Corp.*, 56 F.3d 1448, 1461 (D.C. Cir. 1995); see generally *United States v. SBC Commc’ns, Inc.*, 489 F. Supp. 2d 1 (D.D.C. 2007) (assessing public-interest standard under the Tunney Act); *United States v. U.S. Airways Group, Inc.*, 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the “court’s inquiry is limited” in Tunney Act settlements); *United States v. InBev N.V./S.A.*, No. 08-1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that the court’s review of a consent judgment is limited and only inquires “into whether the government’s determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanism to enforce the final judgment are clear and manageable”).

As the U.S. Court of Appeals for the District of Columbia Circuit has held, under the APPA a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government’s complaint, whether the decree is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. See *Microsoft*, 56 F.3d at 1458–62. With respect to the adequacy of the relief secured by the decree, a court may not “engage in an

unrestricted evaluation of what relief would best serve the public.” *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (quoting *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981)); see also *Microsoft*, 56 F.3d at 1460–62; *United States v. Alcoa, Inc.*, 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *3. Instead:

[t]he balancing of competing social and political interests affected by a proposed antitrust consent decree must be left, in the first instance, to the discretion of the Attorney General. The court’s role in protecting the public interest is one of insuring that the government has not breached its duty to the public in consenting to the decree. The court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is “within the reaches of the public interest.” More elaborate requirements might undermine the effectiveness of antitrust enforcement by consent decree.

Bechtel, 648 F.2d at 666 (emphasis added) (citations omitted).¹

In determining whether a proposed settlement is in the public interest, a district court “must accord deference to the government’s predictions about the efficacy of its remedies, and may not require that the remedies perfectly match the alleged violations.” *SBC Commc’ns*, 489 F. Supp. 2d at 17; see also *U.S. Airways*, 38 F. Supp. 3d at 74–75 (noting that a court should not reject the proposed remedies because it believes others are preferable and that room must be made for the government to grant concessions in the negotiation process for settlements); *Microsoft*, 56 F.3d at 1461 (noting the need for courts to be “deferential to the government’s predictions as to the effect of the proposed remedies”); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant “due respect to the government’s prediction as to the effect of proposed remedies, its perception of the market structure, and its views of the nature of the case”). The ultimate question is whether “the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the ‘reaches of the public interest.’” *Microsoft*, 56 F.3d at 1461 (quoting *United States v. Western Elec. Co.*, 900 F.2d 283, 309 (D.C. Cir. 1990)). To meet this standard,

¹ See also *BNS*, 858 F.2d at 464 (holding that the court’s “ultimate authority under the [APPA] is limited to approving or disapproving the consent decree”); *United States v. Gillette Co.*, 406 F. Supp. 713, 716 (D. Mass. 1975) (noting that, in this way, the court is constrained to “look at the overall picture not hypercritically, nor with a microscope, but with an artist’s reducing glass”).

the United States “need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.” *SBC Commc’ns*, 489 F. Supp. 2d at 17.

Moreover, under *Microsoft*, the court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its complaint, and does not authorize the court to “construct [its] own hypothetical case and then evaluate the decree against that case.” *Microsoft*, 56 F.3d at 1459; see also *U.S. Airways*, 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government’s decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev*, 2009 U.S. Dist. LEXIS 84787, at *20 (“the ‘public interest’ is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged”). Because the “court’s authority to review the decree depends entirely on the government’s exercising its prosecutorial discretion by bringing a case in the first place,” it follows that “the court is only authorized to review the decree itself,” and not to “effectively redraft the complaint” to inquire into other matters that the United States did not pursue. *Microsoft*, 56 F.3d at 1459–60. To inquire about claims that are not in a complaint would violate the separation of powers and aggravate the “constitutional difficulties that inhere in this statute.” See United States’ December 14, 2018 Response to Order to Show Cause, Dkt. #32 at 3–7 (discussing the constitutional difficulties with the Tunney Act); see also *Microsoft* 56 F.3d at 1459; *United States v. Fokker Servs.*, 818 F.3d 733, 738 (D.C. Cir. 2016) (recognizing the “long-settled understandings about the independence of the Executive with regard to charging decisions”); *Heckler v. Chaney*, 470 U.S. 821, 832 (1985) (quoting U.S. Const. art. II, § 3) (recognizing that the decision about which claims to bring “has long been regarded as the special province of the Executive Branch.”).

An amicus brief filed by the AIDS Healthcare Foundation erroneously argues that the 2004 amendments to the Tunney Act overrule *Microsoft*, allowing courts to consider allegations that are not in the complaint.² In fact, however, the amendments addressed a separate issue. In the *Microsoft* opinion, after the court held that the Tunney Act does not allow courts to look beyond the

² Amicus Brief from the AIDS Healthcare Foundation, Dkt. #50-1.

scope of the complaint, the opinion says that a district judge is not obliged to accept a consent decree that “appears to make a mockery of judicial power.” 56 F.3d at 1462. According to legislative history of the 2004 amendments, Congress was concerned that subsequent courts had taken this latter language too far, limiting their review solely to the question of whether “antitrust consent judgments” would make “a mockery of the judicial function.”³ As a result, Congress changed the language of § 16(e) from saying that the court “may” consider the public-interest factors to the court “shall” consider those factors, making them mandatory.⁴ Congress also modified the list of factors, for example, adding a new factor (whether the terms of the judgment are ambiguous⁵), which the *Microsoft* court had already made clear was appropriate to consider, 56 F.3d at 1461–62. Thus, as Senator Hatch observed, “this amendment essentially codifies existing case law.”⁶ See also *SBC Commc’ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments “effected minimal changes” to the Tunney Act review).

Indeed, rather than overruling *Microsoft*, the 2004 amendments reaffirm that courts should focus solely on how the judgment impacts the harms alleged in the complaint by (1) keeping the language in § 16(e) that directs courts to limit their analysis to the competitive impact of the “consent judgment,”⁷ (2) adding language that directs courts to consider competition “in the relevant market or markets,”⁸ and (3) making those considerations mandatory rather than permissive. As Senator Kohl’s floor statement explained, “A mandate to review the impact of entry of the consent judgment upon ‘competition in the relevant market or markets’ . . . will ensure that the Tunney Act review is properly focused on the likely competitive impact of the judgment, rather than extraneous factors irrelevant to the purposes of antitrust enforcement.”⁹

³ Antitrust Criminal Penalty Enhancement and Reform Act of 2004, Pub. L. No. 108-237, tit. II, § 221(a), 118 Stat. 661, 668 (2004) (finding that “it would misconstrue the meaning and Congressional intent in enacting the Tunney Act to limit the discretion of district courts to review antitrust consent judgments solely to determining whether entry of those consent judgments would make a ‘mockery of the judicial function.’”).

⁴ Compare 15 U.S.C. § 16(e) (2004), with 15 U.S.C. § 16(e)(1) (2006).

⁵ 15 U.S.C. § 16 (e)(1)(A).

⁶ 150 Cong. Rec. S3610, at S3613 (daily ed. Apr. 2, 2004).

⁷ 15 U.S.C. § 16(e)(1).

⁸ Compare 15 U.S.C. § 16(e) (2004), with 15 U.S.C. § 16(e)(1)(B) (2006).

⁹ 150 Cong. Rec. S3618 (statement of Sen. Kohl).

Finally, in the 2004 amendments, Congress addressed the Tunney Act review process, adding the unambiguous instruction that “[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.” 15 U.S.C. § 16(e)(2); see also *U.S. Airways*, 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: “[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.” 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). Rather, the procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court’s “scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.” *SBC Commc’ns*, 489 F. Supp. 2d at 11. A court can make its public-interest determination based on the competitive impact statement and response to public comments alone. *U.S. Airways*, 38 F. Supp. 3d at 76; see also *United States v. Enova Corp.*, 107 F. Supp. 2d 10, 17 (D.D.C. 2000) (noting that the “Tunney Act expressly allows the court to make its public interest determination on the basis of the competitive impact statement and response to comments alone”); S. Rep. No. 93-298 93d Cong., 1st Sess., at 6 (1973) (“Where the public interest can be meaningfully evaluated simply on the basis of briefs and oral arguments, that is the approach that should be utilized.”).

IV. The Investigation, the Harm Alleged in the Complaint, and the Proposed Final Judgment

The proposed Final Judgment is the culmination of a thorough, comprehensive investigation conducted by the Antitrust Division of the U.S. Department of Justice into CVS’s proposed acquisition of Aetna. As noted in the Complaint, CVS is one of the largest companies in the United States. It operates the nation’s largest retail pharmacy chain. It owns a large pharmacy benefit manager (“PBM”) called Caremark, which manages the pharmacy benefits for various health plans and negotiates their drug pricing with pharmaceutical companies and retail pharmacies. Through its

subsidiary called SilverScript, CVS is also the nation’s largest provider of individual PDPs, which provide Medicare beneficiaries with insurance coverage for their prescription drugs. Aetna is the nation’s third largest health insurer and, before the divestiture, offered individual PDPs throughout the United States.

Based on the evidence gathered during its investigation, the United States concluded that CVS’s proposed acquisition of Aetna would likely substantially lessen competition for the sale of individual PDPs in the 16 geographic regions where CVS and Aetna are particularly strong, resulting in higher prices, less innovation, fewer choices, and lower-quality individual PDPs for Medicare beneficiaries in these regions. Accordingly, the United States filed a civil antitrust lawsuit to block the acquisition as a violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

The proposed Final Judgment provides an effective and appropriate remedy for the transaction’s likely competitive harm by requiring CVS to divest Aetna’s individual PDP business nationwide. The proposed Final Judgment has several components, which the parties agreed to abide by during the pendency of the Tunney Act proceeding, and which the Court ordered in the Asset Preservation Stipulation and Order of October 25, 2018, Dkt. # 15.

First, CVS must divest both of Aetna’s individual PDP contracts with the Centers for Medicare and Medicaid Services (“CMS”), which is the federal agency that administers the PDP program. Aetna’s individual PDP business was the only portion of Aetna’s business where the merger with CVS would have caused a substantial lessening of competition. Divesting Aetna’s nationwide individual PDP business—and not just Aetna’s business in the regions identified in the Complaint—provides WellCare with the same scale and capabilities to implement a national PDP strategy as Aetna had before the merger. Aetna’s individual PDP contracts were transferred to WellCare on November 29, 2018. From December 2018 to January 2019, WellCare’s enrollment in its legacy PDP plans increased by over 400,000 members nationwide, and its market share grew in all 34 PDP regions. The enrollment in the divested Aetna plans also grew, adding over 140,000 members.¹⁰

¹⁰ See CMS Monthly Enrollment by CPSC for January 2019, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics->

Second, the proposed Final Judgment requires CVS and Aetna to transfer to WellCare (1) data relating to Aetna's individual PDP business, (2) information regarding the amount that Aetna pays to retail pharmacies in exchange for filling prescriptions for Aetna members, and (3) any contracts with brokers that currently sell Aetna's individual PDPs. The transfer of this data, information, and contracts helps ensure that WellCare has sufficient information to negotiate with retail pharmacies and brokers on the same footing as Aetna did before the merger.

Third, during the 60-day period following the sale to WellCare, the proposed Final Judgment has provided WellCare the opportunity to interview and hire Aetna's current employees with expertise related to the individual PDP business. The transfer of data and recruiting of Aetna employees are moving forward according to the terms of the proposed Final Judgment.

The proposed Final Judgment also includes provisions aimed at ensuring that the divested assets are handed off in a seamless and efficient manner, particularly for the two key competitive events for individual PDPs: the submission of bids to CMS each June (for the following year) and open-enrollment season for members, which occurs from October through December. In this case, before the contracts were transferred to WellCare on November 29, 2018, Aetna had already submitted its bids for the divestiture assets and open-enrollment was well under way. Thus, to assist WellCare during the 2019 plan year, CVS must, at WellCare's option, enter into an administrative services agreement to provide WellCare with all of the services required to manage the divestiture assets through the plan year, which ends on December 31, 2019. These services include contracting with pharmacy networks, administering the plans' formularies, and providing back-office support and claims administration functions. Requiring CVS to support and service these plans provides continuity to members who purchased an Aetna individual PDP during the open-enrollment period that ran from October through December 2018 and will ensure that members receive the plans that they have chosen. CVS and WellCare have entered into an administrative services agreement and, since the divestiture, CVS has been providing WellCare with the necessary services to manage the

divestiture assets in 2019 while WellCare has begun preparing for the June 2019 submission of its bid for 2020.

Additionally, CVS and Aetna must allow WellCare to use the Aetna brand for the divestiture assets through December 31, 2019, and CVS and Aetna are prohibited, through 2020, from using the Aetna brand for the CVS individual PDP business that they are retaining. This will provide WellCare with a window to establish a relationship with current Aetna individual PDP beneficiaries and avoid customer confusion.

The proposed Final Judgment also includes robust mechanisms that will allow the United States and the Court to monitor the effectiveness of the relief and to enforce compliance. For example, the proposed Final Judgment provides for the appointment of a monitoring trustee, which the Court appointed on December 3, 2018. As a result, the monitoring trustee, Ms. Julie Myers Wood, is actively working to ensure that the divestiture proceeds appropriately. She has the power and authority to investigate and report on Defendants' compliance with the terms of the Final Judgment and the Asset Preservation Stipulation and Order during the pendency of the divestiture and is required to file reports with the United States every 90 days. In addition, the proposed Final Judgment provides the United States with the ability to investigate Defendants' compliance with the Final Judgment and expressly retains and reserves all rights for the United States to enforce the provisions of the proposed Final Judgment, including its rights to seek an order of contempt from the Court.

Together, the requirements in the proposed Final Judgment ensure that WellCare can step into Aetna's shoes, thereby preserving the competition that the merger would otherwise destroy.

V. Summary of Public Comments and the United States' Response

The United States received 173 comments¹¹ from different categories of commenters. These commenters included advocacy groups, such as the American Medical Association

¹¹ These comments are provided as attachments TC-001 through TC-085. Aside from redactions of personally identifiable information such as personal email addresses, phone numbers, and patient information, the comments are provided in their entirety. Four groups of substantially similar comments are included together as attachments TC-007, TC-020, TC-057 and TC-061. Amicus filings made before the end of the comment period by (1) Consumer Action and U.S. PIRG and (2) PUTT and PSSNY are included as attachments TC-023 and TC-060, respectively.

(“AMA”), the American Antitrust Institute (“AAI”), Consumer Action and U.S. PIRG, and the Medical Society of the State of New York (“MSSNY”). In addition, the United States received comments from several groups representing pharmacists that compete with CVS, including the National Community Pharmacists Association (“NCPA”), the Pharmacists Society of the State of New York (“PSSNY”), and Pharmacists United for Truth and Transparency (“PUTT”), as well as approximately 120 individual pharmacies. The United States also received a handful of comments from business associations and healthcare industry associations.

The comments can be grouped into four categories: (1) comments about WellCare's suitability as a divestiture buyer, including whether it will have sufficient assets, expertise, and incentives to preserve competition; (2) comments related to the vertical combination of CVS's pharmacy and PBM businesses with Aetna's health insurance businesses; (3) other miscellaneous comments, including questions about whether the merger will facilitate coordination, have anticompetitive effects in various healthcare markets, increase entry barriers in the PBM or health insurance markets, or reduce PBM competition by eliminating Aetna as a PBM competitor; and (4) comments in support of the merger. The Court's analysis under the Tunney Act should focus on the first category of comments, as they are the only comments that relate to whether the proposed remedy addresses the harms alleged in the Complaint. See *Microsoft*, 56 F.3d at 1459.

A. Comments Regarding WellCare's Suitability as a Divestiture Buyer and Ability to Compete Effectively

WellCare has extensive experience and qualifications in the individual PDP market and, with the assets provided by the proposed Final Judgment, is a suitable divestiture buyer. Although the AMA, Consumer Action and U.S. PIRG, NCPA, PUTT and PSSNY, and numerous independent pharmacies, raised concerns regarding WellCare as the buyer of the divested assets, none of those concerns is valid for the reasons explained below.¹² These commenters raised six primary objections: (1) WellCare will not compete as effectively as Aetna; (2) WellCare will not operate independently of CVS because WellCare uses CVS's PBM, Caremark; (3) some

¹² TC-003, TC-015, TC-023, TC-024, TC-047, TC-054, TC-059, TC-060, TC-061, TC-063, TC-064, TC-072, TC-080, TC-081, and TC-085.

health insurance divestitures have not been successful, indicating that the divestiture to WellCare may not be successful; (4) the divestiture creates new structural concerns in the markets for the sale of individual PDPs; (5) the divestiture raises concerns related to WellCare's license of the Aetna brand; and (6) the divestiture sales price is too low.

1. WellCare is an experienced and effective competitor.

WellCare has experience and qualifications in government-funded insurance programs. Despite this, commenters said that WellCare may not compete as effectively as Aetna in individual PDP markets because WellCare is smaller and less capable than Aetna and because WellCare is not purchasing a stand-alone business unit; these concerns are misplaced.¹³ Although Aetna's overall membership is larger when taking into account its commercial business, WellCare is already a large and established insurer that has competed in the markets for individual PDPs for over a decade. WellCare is a Fortune 200 company with over 12,000 employees, 5.5 million members, and a market capitalization of approximately \$15 billion. Even before acquiring over 2.1 million members from Aetna as part of the divested business, WellCare had attracted nearly 1.1 million individuals in its PDPs throughout the United States. WellCare is thus starting from a strong base and its acquisition of all of Aetna's individual PDP business will enable WellCare to improve its PDP business and become a more significant competitor.

Some commenters expressed a concern that, despite its size, WellCare will not be as competitive as Aetna because Aetna's overall health insurance business was larger than that of WellCare.¹⁴ Before the divestiture, however, WellCare already competed successfully as a smaller competitor than Aetna. From 2018 to 2019, WellCare organically grew its business by over 40 percent, from approximately 1 million members to over 1.4 million members.¹⁵ More importantly, with the acquisition of Aetna's individual PDP business, WellCare's total individual

PDP membership is well over three million members, approximately 50 percent more than Aetna's pre-divestiture individual PDP membership. Following the divestiture, WellCare will be well-positioned to achieve any benefits of scale that Aetna had enjoyed in its individual PDP business, enabling it to be an even more formidable competitor than it previously was and ensuring that the remedy is well within the "reaches of the public interest," as required under the Tunney Act. See *Microsoft*, 56 F.3d at 1461.

Concerns that WellCare is not getting enough assets or a stand-alone business unit from Aetna misunderstand the context of the remedy here.¹⁶ The Antitrust Division's experience, as reflected in the 2004 Policy Guide to Merger Remedies,¹⁷ is that in some instances, an in-market buyer does not need a stand-alone business unit to be successful: "The Division will approve the divestiture of less than an existing business entity if the evidence clearly demonstrates that certain of the entity's assets already are in the possession of, or readily obtainable in a competitive market by, the potential purchaser."¹⁸

Consistent with this principle, the proposed Final Judgment ensures that WellCare will have all that it needs to preserve competition in the sale of individual PDPs. WellCare has purchased Aetna's entire individual PDP business throughout the United States, including the relevant contracts, the right to hire employees, and access to all relevant data. Focusing on a stand-alone "business unit" in this case ignores the critical fact that WellCare already offers individual PDPs throughout the United States, is licensed in all 50 states, and has scalable in-house capabilities that it does not need to duplicate. These capabilities include experience competing in individual PDP markets throughout the country, actuarial expertise, as well as clinical and administrative resources. Because of these existing capabilities, WellCare does not need to acquire a stand-alone business unit to compete for the sale of individual PDPs. Instead, WellCare is

acquiring key competitive assets that complement its existing capabilities and allow WellCare to step quickly and effectively into Aetna's shoes as a significant competitor for the sale of individual PDPs.

Despite WellCare's in-market expertise, the joint comments by Consumer Action and U.S. PIRG¹⁹ and PUTT and PSSNY²⁰ erroneously argue that WellCare is similarly situated to Molina, the proposed divestiture buyer of Aetna's Medicare Advantage business that Judge Bates rejected in an opinion enjoining Aetna's proposed acquisition of Humana.²¹ This concern fails to appreciate that WellCare is differently situated than Molina in several ways. Unlike Molina, which had "made forays into the individual Medicare Advantage market" but never succeeded,²² WellCare has consistently maintained a presence in the individual PDP business since the program's inception in 2006. Also, Aetna proposed to divest only small portions of each of the merging parties' Medicare Advantage business to Molina. In contrast, while WellCare has not purchased a stand-alone business unit, it has purchased Aetna's entire individual PDP business, including Aetna's business outside the affected geographic markets. Medicare Advantage products also differ significantly from individual PDP products. In addition to the pharmacy networks used by PDPs, Medicare Advantage products require a comprehensive network of hospitals, doctors, and other healthcare providers at competitive rates. In *Aetna/Humana*, Molina had no presence at all in 89 percent of the counties referenced in the United States' complaint and no Medicare presence in 95 percent of the counties, so the company would have needed to build its own provider network to compete in the market.²³ By contrast, WellCare already has an extensive pharmacy network that it uses to sell individual PDPs throughout the United States and will not have to assemble any new networks in any region to offer individual PDPs. Thus, unlike Molina in *Aetna/Humana*, WellCare is both purchasing an entire business and is a qualified buyer with the assets and capabilities to continue competing successfully.

¹⁶ See, e.g., TC-024, TC-060.

¹⁷ This is the operative guide on remedies following the September 25, 2018 withdrawal of the 2011 Policy Guide to Merger Remedies. See Makan Delrahim, *It Takes Two: Modernizing the Merger Review Process*, Remarks at the 2018 Global Antitrust Enforcement Symposium (September 25, 2018), available at <https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-2018-global-antitrust>.

¹⁸ Antitrust Division Policy Guide to Merger Remedies, October 2004, at 14, available at <https://www.justice.gov/sites/default/files/atr/legacy/2011/06/16/205108.pdf>.

¹⁹ TC-023 at 3–4, TC-024 at 5–6.

²⁰ TC-060 at 21.

²¹ *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 73 (D.D.C. 2017).

²² *Id.* at 62.

²³ *Id.* at 65.

¹³ See, e.g., TC-003, TC-024, and TC-060.

¹⁴ See, e.g., TC-003, TC-024.

¹⁵ See CMS Monthly Enrollment by CPSC for January 2019, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Monthly-Enrollment-by-Contract-Plan-State-County-Items/Monthly-Enrollment-by-CPSC-2019-01.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending>.

2. WellCare is an independent competitor to CVS.

Although some commenters raised concerns that WellCare will not operate independently of CVS because WellCare uses Caremark (which CVS owns) as its PBM,²⁴ the United States carefully considered this relationship in evaluating WellCare's suitability as the divestiture buyer and ultimately concluded that WellCare will continue to be an independent competitor to CVS for several reasons.

First, CVS has no governance control over WellCare. Rather, WellCare is a separate corporate entity with an independent board of directors. Second, CVS and WellCare do not have common financial incentives. As a separate company, WellCare is driven to focus on its own business and compete vigorously against CVS. Third, while WellCare may make the independent business decision to use Caremark rather than its other PBM options, nothing in the proposed Final Judgment requires WellCare to do so. In fact, WellCare recently announced that it is putting its PBM services contract out to bid in the summer of 2019.²⁵ Fourth, WellCare recently acquired a small PBM called Meridian, which improves WellCare's ability to provide its own PBM services. Finally, Caremark's business has internal firewalls designed to prevent insurance customers' information from being shared with SilverScript and other insurance customers. This means that WellCare, like all of Caremark's health plan customers, can make its own independent business decisions with the protections these firewalls provide against the risk that SilverScript, or any other Caremark customer, will have access to competitively sensitive information or advance knowledge of its business plans and other competitive decisions.

Because WellCare retains control of the divestiture assets and has the financial incentive to use them in its best interests, rather than CVS's, WellCare's relationship with Caremark does not change the conclusion that the proposed remedy is in the public interest. This conclusion is bolstered by the success of Aetna's individual PDP plans, which used Caremark for PBM services before the merger, showing that a relationship with Caremark does not

impede an individual PDP's competitiveness. Similarly, WellCare has also competed against CVS's SilverScript business for many years despite using Caremark for PBM services.

Other comments incorrectly suggest that, because the proposed Final Judgment includes transition services agreements for 2019, WellCare will not operate the divestiture assets independently of CVS.²⁶ As described above, the proposed Final Judgment requires that, at WellCare's option, CVS must enter into an administrative services agreement to provide WellCare with all of the services required to manage the divestiture assets through the 2019 plan year. CVS must offer these services at the direction of WellCare and subject to the review of both the monitoring trustee and the United States, whose oversight will likely deter any attempts to undermine WellCare's competitiveness.

The transition services agreements are also only in place through 2019. This temporary arrangement provides continuity to members who purchased an Aetna individual PDP during the open-enrollment period that ran from October through December 2018, but ends when plans for 2020 will become effective. These transition services are necessary for the seamless and efficient transition of Aetna's individual PDP business to WellCare. Importantly, the agreements do not affect the prices, design, coverage amounts, and other terms of the plans WellCare is now offering to seniors. Rather, these terms have been fixed for all of 2019.

Further, the monitoring trustee is closely tracking CVS's compliance with the terms of the transition services agreements. CVS's obligations are clearly stated in the proposed Final Judgment, and the monitoring trustee is already ensuring that CVS is fulfilling its responsibilities. Because Aetna's contracts with CMS, as well as the related data, have been transferred in accordance with the terms of the proposed Final Judgment, WellCare has all the assets it needs to independently prepare for the next competitive event—the June 2019 submission of the bid for 2020—which is not impacted by the transition services agreements.

3. Prior health insurance merger remedies do not cast doubt on the divestiture.

In 2012, the United States required Humana Inc. and Arcadian Management Services Inc. to divest assets relating to Arcadian's Medicare Advantage

business in 51 counties in five states in order for Humana to proceed with an acquisition of Arcadian.²⁷ Several commenters looked at this and other divestitures in hindsight and conclude that they failed or that divestitures in general are not successful remedies.²⁸ As a general matter, however, the factual circumstances in every divestiture are different. Furthermore, the concerns that the experience of prior divestitures indicates that the divestiture to WellCare will fail in this instance are wrong because the circumstances here are different.

Indeed, there are several key differences between this divestiture and the ones in *Humana/Arcadian*, the most important of which is the scope of the divestiture. In *Humana/Arcadian* the divestiture did not constitute an entire business, as it included only 12,700 covered lives in 51 rural counties and was split between three different acquirers. In contrast, CVS has divested Aetna's entire individual PDP business, consisting of over two million members and including assets outside the markets described in the Complaint. Additionally, similar to *Molina in Aetna/Humana*, the *Humana/Arcadian* divestitures concerned Medicare Advantage products and some of those divestitures went to buyers that did not have Medicare Advantage provider networks in the divested markets. In contrast, WellCare already has pharmacy networks in every region of the United States. Divesting the entire line of business to WellCare, a well-positioned buyer, will help ensure that WellCare continues to compete effectively and capture additional economies of scale across its entire business.

Despite these factual differences, commenters also note that WellCare was the buyer of one set of divested assets in *Humana/Arcadian* and wrongly suggest that, because that divestiture failed, this one likely will too.²⁹ As described above, the two divestitures are substantially different. In *Humana/Arcadian*, WellCare acquired fewer than 5,000 lives in two counties in Arizona. In contrast, WellCare is acquiring over 2.1 million individual PDP lives across the United States from Aetna. Additionally, as described above,

²⁴ See, e.g., TC-003, TC-015, TC-060, TC-061, and TC-080.

²⁵ See "WellCare Fourth Quarter 2018 Earnings Conference Call Transcript" (February 5, 2019) available at <https://www.fool.com/earnings/call-transcripts/2019/02/05/wellcare-health-plans-inc-wcg-q4-2018-earnings-con.aspx> (last visited February 13, 2019).

²⁶ TC-003, TC-023, and TC-024.

²⁷ See "Justice Department Requires Divestitures in Humana Inc.'s Acquisition of Arcadian Management Services Inc.," available at <https://www.justice.gov/opa/pr/justice-department-requires-divestitures-humana-incs-acquisition-arcadian-management-services>.

²⁸ TC-003, TC-023, TC-024, and TC-060.

²⁹ TC-023, TC-024, and TC-060; see also Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

WellCare did not have a Medicare Advantage provider network in Arizona before the divestiture in *Humana/Arcadian* while WellCare already has an established pharmacy network in place that it can use for the PDP business it is acquiring from Aetna. Further, WellCare has grown significantly as a company since 2012—more than doubling from 2.7 million³⁰ members to 5.5 million³¹—and overhauled its leadership team, including the CEO, CFO, CIO, CMO, and the EVP for Clinical Operations.³² Because of the larger scale of the current divestiture, WellCare's growth as a health insurance company, and its experience and existing capabilities with individual PDPs, WellCare's performance with the *Humana/Arcadian* assets does not indicate how successful it will be with Aetna's PDP business. Because a district court "must accord deference to the government's predictions about the efficacy of its remedies," *SBC Commc'ns*, 489 F. Supp. 2d at 17, and because the divestiture to WellCare is readily distinguishable from the ones that commenters allege failed in *Humana/Arcadian*, the Court should afford deference to the government's prediction of a successful divestiture in this instance.

4. The remedy does not create new structural concerns in the markets for individual PDPs.

The AMA incorrectly argues that, because WellCare and Aetna both compete in all 34 Medicare regions, the divestiture itself creates competitive concerns simply by reducing the number of competitors in every region.³³ The AMA further alleges that, in seven regions, the divestiture "would potentially raise significant competitive concerns [that] often warrant scrutiny" because it exceeds certain Herfindahl–Hirschman Index ("HHI") thresholds in the Horizontal Merger Guidelines.³⁴

HHIs are a commonly accepted measure of market concentration and are calculated by squaring the market share of each firm competing in the market and then summing the resulting numbers.³⁵ The U.S. Department of

Justice, consistent with the Federal Trade Commission, generally considers markets in which the HHI is between 1,500 and 2,500 points to be moderately concentrated, and considers markets in which the HHI is in excess of 2,500 points to be highly concentrated.³⁶ Transactions that increase the HHI by more than 100 points in moderately concentrated markets or between 100 and 200 points in highly concentrated markets "potentially raise significant competitive concerns and often warrant scrutiny."³⁷ Transactions that increase the HHI by more than 200 points in highly concentrated markets are "presumed to be likely to enhance market power."³⁸

In this case, although some regions fall into the category of "potentially" raising concerns under the Horizontal Merger Guidelines after the divestiture, no regions are above the threshold for "presumed" concerns. Moreover, as described in the 2010 Horizontal Merger Guidelines, while the United States does use HHIs and other concentration statistics, such as the number of firms in the market, as an important part of its investigative toolkit, "[t]he purpose of these thresholds is not to provide a rigid screen to separate competitively benign mergers from anticompetitive ones . . . [r]ather, they provide one way to identify some mergers unlikely to raise competitive concerns and some others for which it is particularly important to examine whether other competitive factors confirm, reinforce, or counteract the potentially harmful effects of increased concentration."³⁹ Consistent with these principles, the United States considered the strength of WellCare, Aetna, and their competitors in all 34 PDP regions. The combined market share of Aetna's and WellCare's individual PDP businesses does not exceed 25 percent in any region. The United States determined that the combination of Aetna's and WellCare's PDP business was not likely to substantially lessen competition, in part due to the presence of other significant competitors—including CVS's SilverScript product—in every market.

5. The licensing provisions related to the Aetna brand protect WellCare's ability to compete using the divested assets.

Under Section IV.I. of the proposed Final Judgment, Aetna is required to

license the Aetna brand to WellCare for use with the divested business only for 2019. For 2020, Section IV.J. of the proposed Final Judgment prohibits CVS from using the Aetna brand for the sale of individual PDPs. Misunderstanding these provisions, the joint comment from Consumer Action and U.S. PIRG raises concerns that WellCare's one-year license to the Aetna brand fails to create an incentive to properly invest in the Aetna brand name.⁴⁰ The proposed Final Judgment, however, is not meant to give WellCare a long-term incentive to invest in the Aetna brand name. Rather, these provisions give WellCare a two-year opportunity to establish its relationship with the customers of the divested plans without a competing Aetna-branded individual PDP plan. Given that, as previously explained, the divestiture improves WellCare's established ability to compete for PDP customers, these provisions further enhance the effectiveness of the proposed Final Judgment.

6. The sales price does not cast doubt on WellCare's intention to compete.

Several commenters raise misplaced concerns related to the price paid by WellCare.⁴¹ For example, the joint comment from Consumer Action and U.S. PIRG estimates the divestiture purchase price to be \$45 per life and then claims—without evidence—that this "seems like a very cheap price."⁴² In some cases, a low purchase price may raise concerns whether a proposed divestiture buyer will be a successful competitor.⁴³ As described in the 2004 Policy Guide to Merger Remedies, "the purchase price will not be approved if it clearly indicates that the purchaser is unable or unwilling to compete in the relevant market."⁴⁴ The Policy Guide also states, however, that "a successful divestiture does not depend on the price paid for the assets."⁴⁵ Rather, a low price "may simply mean the purchaser is getting a bargain" and "if the Division has other sufficient assurances that the proposed purchaser intends to compete in the relevant market, the Division will not require . . . [a certain] price."⁴⁶

³⁰ See "WellCare 2011 Annual Report", available at <http://ir.wellcare.com/file/4091918/Index?KeyFile=1500074253>.

³¹ See "WellCare Corporate Overview", available at <https://www.wellcare.com/en/Corporate/Company-Overview> (last visited February 13, 2019).

³² See "WellCare Corporate Management Team", available at <https://www.wellcare.com/Corporate/Management-Team> (last visited February 13, 2019).

³³ TC-030 at 6-7.

³⁴ *Id.*

³⁵ For example, for a market consisting of four firms with shares of 30, 30, 20, and 20 percent, the HHI is 2,600 (30² + 30² + 20² + 20² = 2,600).

³⁶ See U.S. Department of Justice & FTC, Horizontal Merger Guidelines § 5.3 (2010), available at <https://www.justice.gov/atr/file/810276/download>.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ TC-023, TC-024; see also TC-003.

⁴¹ TC-003, TC-023, TC-024, and TC-060.

⁴² TC-023 at 5, TC-024 at 7.

⁴³ See, e.g., *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 72 (D.D.C. 2017) (citing to an "extremely low" purchase price as evidence that the divestiture buyer was not likely to be able to replace the competition lost by the merger).

⁴⁴ Antitrust Division Policy Guide to Merger Remedies, October 2004, at 33 available at <https://www.justice.gov/sites/default/files/atr/legacy/2011/06/16/205108.pdf>.

⁴⁵ *Id.*

⁴⁶ *Id.* at 34.

In this case, the Antitrust Division has those assurances. The United States thoroughly vetted WellCare, which has offered individual PDPs since the program's inception in 2006 and has recently experienced strong organic growth.⁴⁷ The United States interviewed WellCare's executives, reviewed its business plans, and discussed WellCare with relevant third parties. Based on these efforts, the United States believes that WellCare will continue to compete in individual PDPs, a market it has participated in for over a decade. The commenters do not provide any evidence that their estimated purchase price undermines this conclusion.

B. Comments Related to the Vertical Aspects of CVS's Acquisition of Aetna

Asking the Court to go outside the permissible scope of review under the Tunney Act, commenters also raise vertical concerns about the merger combining CVS's pharmacy and PBM businesses with Aetna's health insurance businesses, alleging that the merger will enable CVS to use its assets to harm competitors. CVS can be viewed as competing at three different levels of the healthcare industry: (1) the sale of drugs through channels such as retail, mail order, and long-term care pharmacies; (2) the provision of PBM services that are offered to insurers, including the negotiation of rates with pharmaceutical manufacturers and the negotiation of coverage networks with pharmacies; and (3) the sale of various types of insurance, including individual PDPs. CVS competes at all three of these levels through its branded retail, long-term care, and other pharmacies; through its PBM, Caremark; and through SilverScript, its individual PDP. Aetna competes with SilverScript at the third level, and offers additional types of insurance, but does not offer stand-alone PBM services or own any retail pharmacies of its own.

Recognizing that CVS and Aetna do not compete against each other either at the retail pharmacy level or the PBM level, commenters nonetheless raise two categories of vertical concerns relating to the merger: input foreclosure and customer foreclosure concerns, which are explained below. Commenters also raise vertical concerns about CVS's common ownership of its retail pharmacies and Caremark, its PBM,

which CVS owned long before it sought to acquire Aetna and is unrelated to the current merger.

The United States investigated the potential for vertical harms from the merger by obtaining and reviewing documents as well as interviewing industry participants. For the reasons outlined below, the United States concluded that vertical harms were unlikely to occur and did not allege any harm related to vertical concerns in its Complaint. The vertical concerns therefore are outside the scope of this Tunney Act proceeding. *See* United States' December 14, 2018 Response to Order to Show Cause, Dkt. #32, at 3–7. Responding to the AAI's comment that there are benefits to transparency, the United States nonetheless describes the commenters' concerns and responds below.

1. Input foreclosure is unlikely to occur and is beyond the scope of the Complaint.

Although several comments raise the possibility that the merged firm will harm competition in the sale of health insurance by raising the cost of important services or products that CVS provides to insurers that compete with Aetna, which is known as input foreclosure, the United States considered this possibility and determined that input foreclosure is unlikely to be profitable for CVS. In particular, commenters argue that CVS will deny or restrict health insurance rivals' access to inputs at two different levels of the supply chain: First, commenters⁴⁸ allege that the company will not make its pharmacies available to competing health plans or will otherwise disadvantage rival plans by raising pharmacy costs. Second, commenters⁴⁹ allege that Caremark will not make its PBM services available to competing health plans or will raise the prices for its PBM services to rival plans.⁵⁰ Neither is likely to occur.

⁴⁸ TC-001, TC-002, TC-003, TC-023, and TC-024; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁴⁹ TC-001, TC-002, TC-003, TC-023, TC-024, TC-048, TC-054, and TC-057.

⁵⁰ Additionally, some commenters also allege that CVS is foreclosing 340B administrators from its retail pharmacies. *See* TC-066, TC-068. 340B administrators offer services to assemble and administer pharmacy networks that provide rebates to qualified hospitals. CVS competes with these administrators through a subsidiary called Wellpartner. These commenters allege that CVS does not allow its pharmacies to participate in 340B networks unless Wellpartner is selected as the hospital's 340B administrator, which would be a form of input foreclosure. CVS's acquisition of Aetna does not relate to the 340B market or affect shares in that market. In part for this reason, the United States did not allege anticompetitive effects

As noted in a set of questions and answers issued on the same day the Complaint and proposed Final Judgment were filed, the United States carefully considered these issues as part of its investigation.⁵¹ The evidence showed that CVS is unlikely to be able to profitably raise its PBM or retail pharmacy costs post-merger. If CVS were to raise prices at any level of the supply chain, it would lose customers to competing PBMs or retail pharmacies, and the merged entity likely would not be able to offset these losses by capturing additional health insurance customers. For these reasons, the United States did not allege input foreclosure in its Complaint, making this issue beyond the scope of this Tunney Act proceeding.

Despite the evidence, the AMA also argues that the divestiture will fail because WellCare will be foreclosed from pharmacy and PBM services.⁵² In effect, this argument asserts that the input foreclosure described above will occur and will be directed at WellCare. As discussed above, the United States concluded that such foreclosure—whether directed at WellCare or any other insurer—is unlikely to occur. Furthermore, even before the divestiture, WellCare (and Aetna) competed successfully against CVS's SilverScript PDP business despite the vertical relationship between SilverScript and Caremark. With the divestiture, CVS's share of the individual PDP market will not grow, so the merger will not increase CVS's incentive or ability to foreclose its PDP rivals—including WellCare—from CVS pharmacies or Caremark.

2. Customer foreclosure is unlikely to occur and is beyond the scope of the Complaint.

Other comments allege that the merged firm would harm pharmacies by denying them access to Aetna members, even though the merger does not significantly increase CVS's incentive to engage in this behavior, which is known as "customer foreclosure."⁵³ Commenters—primarily independent pharmacies that compete with CVS—allege that Caremark favors CVS

from the merger related to CVS or Wellpartner's practices, placing the concerns of these commenters outside of the Court's Tunney Act review. *See* Dkt. #32, at 3–7.

⁵¹ *See* "United States v. CVS and Aetna Questions and Answers for the General Public," available at <https://www.justice.gov/opa/press-release/file/1099806/download>.

⁵² TC-003 at 12.

⁵³ TC-002, TC-023, TC-024, TC-035, TC-048, TC-059, TC-060, TC-070, TC-076, TC-078; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁴⁷ *See* CMS Monthly Enrollment by CPSC for January 2019, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAAdvPartDenrolData/Monthly-Enrollment-by-Contract-Plan-State-County-Items/Monthly-Enrollment-by-CPSC-2019-01.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending>.

pharmacies in its reimbursements.⁵⁴ The commenters allege that this favoritism can be observed in Caremark programs such as mandatory mail order, which steers customers away from independent pharmacies.⁵⁵ Commenters also allege that Caremark manipulates reimbursement to independent pharmacies, sometimes later offering to buy them and turn them into CVS stores,⁵⁶ and that several states are investigating these practices.⁵⁷ From these allegations, these commenters incorrectly conclude that CVS is likely to use Aetna to steer additional customers away from rival pharmacies, causing them harm.

The United States takes these allegations seriously and considered them during its investigation. Generally, the United States considers the merging companies' prior acts when evaluating the likely effects of a transaction, but mergers are illegal under the Clayton Act only if they will likely substantially lessen competition in a relevant market.⁵⁸ Based on its investigation, the United States determined that CVS's acquisition of Aetna likely would not result in an anticompetitive customer foreclosure strategy, particularly given Aetna's small share in many commercial health insurance markets. The combination of Aetna's small share of retail pharmacy purchases in many areas, competition from rival insurers who would win additional sales if Aetna provided a less desirable pharmacy network, and other factors make it unlikely that this strategy would be profitable for CVS. Therefore, the United States did not allege customer foreclosure in its Complaint, placing this issue beyond the scope of this Tunney Act proceeding. *See* Dkt. #32, at 3–7. Consequently, these comments do not provide a basis for rejecting the proposed Final Judgment. *See U.S. Airways*, 38 F. Supp. 3d at 76 (“Moreover, the Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint. . . .”) (quoting *United*

States v. Graftech Int’l Ltd., No. 1:10-CV-02039-RMC, 2011 WL 1566781, at *13 (D.D.C. Mar. 24, 2011)).

3. Vertical concerns are not addressable under the Tunney Act’s standard of review.

Although their comments are outside the scope of the Court’s Tunney Act review because the Complaint does not allege vertical harms, some commenters weighed in on the standard of review under the Tunney Act⁵⁹ or commented that the Court may still consider vertical concerns if the Complaint is drafted so narrowly as to make a “mockery of judicial power,” an argument that is unsupported by the caselaw, as discussed above.⁶⁰ Indeed, as the D.C. Circuit recognized in *Microsoft*, 56 F.3d at 1459, a district court may not evaluate the scope of the complaint during a Tunney Act review, even if the court believes that additional claims would have been justified. While a court is not obliged to accept a consent decree that “makes a mockery of judicial power,” *id.* at 1462, under *Microsoft* that standard applies to the consent decree—not the complaint—and subsequent cases suggesting otherwise are inconsistent with *Microsoft*.

In any event, neither the Complaint nor the proposed Final Judgment is drafted so narrowly as to make a mockery of judicial power. To the contrary, the Complaint is significant in scope: it challenges anticompetitive harm in 16 broad regions, encompassing 22 states, affecting millions of seniors. The proposed Final Judgment goes even further, addressing the anticompetitive harm with the nationwide divestiture of Aetna’s entire individual PDP business.

Furthermore, the fact that the divestiture represents a small fraction of the underlying \$69 billion merger is not relevant to the public-interest determination and is not a basis for concluding that the proposed remedy makes a mockery of the judicial process, as some commenters suggest.⁶¹ Courts have routinely found proposed judgments to be in the public interest when the United States challenged only a small part of a large transaction,⁶² and

settlements are often ideal in these situations because they allow parties to proceed with transactions that could otherwise benefit consumers. Because Aetna was the nation’s third-largest health insurance company, it is not surprising that its individual PDP business, while substantial, represents only a small percentage of the company’s total value. The United States made these arguments in more detail in its December 14, 2018 Response to Order to Show Cause, *see* Dkt. #32, and incorporates that pleading herein by reference.

C. Other Miscellaneous Comments

Even though CVS and Aetna significantly compete against each other only in the sale of individual PDPs, several commenters raised irrelevant concerns related to other markets, including whether the merger will increase entry barriers in either the PBM or health insurance markets,⁶³ or reduce PBM competition by eliminating Aetna as a potential entrant in the PBM market.⁶⁴ During its investigation, the United States seriously considered whether the merger likely would harm competition in the PBM and health insurance markets, including by increasing entry barriers and eliminating Aetna as a PBM competitor. Among other things, the United States obtained and reviewed documents and interviewed industry participants about these issues. In reviewing such information, the United States determined that the evidence did not show that the merger likely would harm competition in these areas. Accordingly, the Complaint did not allege that CVS’s acquisition of Aetna would harm competition in PBM and health insurance markets other than the sale of individual PDP plans. These comments are thus beyond the purview of the Tunney Act and do not provide a basis for rejecting the proposed Final Judgment. *See U.S. Airways*, 38 F. Supp. 3d at 76 (“[T]he Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations

transaction); *United States v. United Technologies Corp. and Goodrich Corp.*, 1:12-cv-01230 (D.D.C. July 26, 2012) (complaint alleging harm in only two product markets, resulting in a divestiture of businesses expected to generate approximately \$395 million in annual revenues, in challenge to \$18.4 billion transaction); *United States v. InBev N.V./S.A. et al.*, 1:08-cv-01965 (D.D.C. Nov. 14, 2008) (complaint alleging harm in only three regions of upstate New York in challenge to InBev’s proposed acquisition of Anheuser-Busch for approximately \$52 billion).

⁶³ TC-002, TC-003.

⁶⁴ TC-001, TC-003; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁵⁴ TC-001, TC-002, TC-004 TC-012, TC-013, TC-016, TC-017, TC-021, TC-023, TC-024, TC-027, TC-031, TC-032, TC-033, TC-034, TC-039, TC-043, TC-044, TC-045, TC-050, TC-059, TC-060, TC-065, TC-075, TC-076, TC-080, TC-083, TC-085.

⁵⁵ TC-001, TC-002, TC-016, TC-020, TC-021, TC-027, TC-035, TC-039, TC-045, TC-046, TC-054, TC-059, TC-061, TC-062, TC-074, TC-080, TC-081.

⁵⁶ TC-004, TC-013, TC-017, TC-023, TC-024, TC-025, TC-031, TC-032, TC-033, TC-038, TC-039, TC-046, TC-061, TC-064, TC-074; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁵⁷ TC-016, TC-031, TC-044, TC-054, TC-059, TC-060, TC-061, TC-063, TC-064, TC-072, TC-078, TC-080, TC-081, TC-082, TC-083; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁵⁸ *See* 15 U.S.C. § 18.

⁵⁹ TC-001, TC-002, TC-003, TC-023, TC-024, TC-060; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁶⁰ TC-001, TC-002, TC-023, TC-024, TC-059, and TC-060; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁶¹ TC-001; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁶² *See United States v. Parker-Hannifin Corp. and CLARCOR Inc.*, 1:17-cv-01354 (D. Del. Sept. 26, 2017) (complaint alleging harm in only two product markets, which resulted in a divestiture of a business with annual revenues of approximately \$60 million, in challenge to \$4.3 billion

that the United States has alleged in its Complaint.”) (internal citation omitted).

Although some commenters expressed concern about concentration in the PBM market, these concerns are misplaced because Aetna does not provide stand-alone PBM services. These commenters state that only three companies—Caremark, ESI, and Optum—control over 80% of the PBM marketplace⁶⁵ and are simply too powerful,⁶⁶ with the ability to harm pharmacies, including by forcing “take it or leave it” contracts on independent pharmacies. The commenters also complain about PBM business practices, such as “spread pricing” on pharmaceuticals, which the commenters allege limits transparency and harms independent pharmacies.⁶⁷ Additionally, the AMA and other commenters raised concerns that the vertically integrated PBM/health insurers (Cigna–Express Scripts, Optum Rx–United Healthcare, and CVS–Aetna) would have increased incentives following the merger to coordinate by bidding less aggressively for PBM contracts that would strengthen their health insurer rivals or that the large vertically integrated PBM/health insurers would have stronger incentives to prevent market entry by other PBMs or the introduction of innovative drug business models.⁶⁸ The merger, however, does not significantly increase concentration in the PBM market because Aetna does not offer stand-alone PBM services. Also, these comments do not relate to whether the proposed Final Judgment reasonably addresses the harms alleged in the Complaint. Therefore, they are well beyond the scope of this Tunney Act proceeding and do not provide a basis for rejecting the proposed Final Judgment. *See U.S. Airways*, 38 F. Supp. 3d at 76 (“[T]he Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint.”) (internal citation omitted).

Some commenters raised concerns about the effectiveness of firewalls at

Caremark, despite CVS’s commercial incentive to maintain those firewalls. The AAI expressed concerns that ineffective firewalls would allow Caremark to facilitate coordination among health insurers that use it as a PBM.⁶⁹ The United States investigated this possibility and determined that CVS is commercially incentivized to maintain firewalls because that customers could switch to an alternative PBM if their information were not kept confidential. MSSNY raised a related concern regarding the potential for consumer data breaches due to data being shared between the merged entities, but CVS already handles sensitive consumer data from Caremark’s PBM business. Nothing about the merger changes CVS’s incentive or ability to protect this information.

Other commenters applied the wrong legal standard when they argued that the Court should reject the settlement because consumers may not benefit from the merger of CVS and Aetna. The AAI and the joint comment from Consumer Action and U.S. PIRG⁷⁰ argue that there is little evidence that past vertical mergers have benefitted consumers, and several commenters⁷¹ suggested that there is no evidence that cost savings will be passed through to customers. Mergers, however, are illegal under the Clayton Act only if they substantially lessen competition in a relevant product market, not if they fail to pass on benefits to consumers in markets where competition likely will not be substantially lessened.⁷² Consequently, these comments do not provide a basis for rejecting the proposed Final Judgment.

Some commenters raised other concerns that are beyond the scope of the Complaint in this case. For example, several commenters, including the MSSNY, said that the merger would harm physicians and other healthcare providers in a number of ways, including through steering patients away from physician groups or by imposing administrative burdens on physicians.⁷³ They also argue that these actions would harm patients. Without relating their concerns to the merger, other commenters allege that the

pharmacy⁷⁴ or insurance⁷⁵ markets are concentrated, raise concerns relating to CVS’s existing pricing practices,⁷⁶ note that CVS is involved in an ongoing federal whistleblower case,⁷⁷ or complain about CVS’s long-term care pharmacy.⁷⁸ As these comments do not relate to whether the proposed Final Judgment reasonably addresses the harms alleged in the Complaint, they are well beyond the scope of this Tunney Act proceeding and do not provide a basis for rejecting the proposed Final Judgment. *See U.S. Airways*, 38 F. Supp. 3d at 76 (“[T]he Court’s role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint.”) (internal citation omitted).

D. Comments in Support of the Merger

Twenty-six commenters expressed support for the merger or praised CVS’s business practices.⁷⁹ Commenters, including the California Asian Pacific Chamber of Commerce, Connecticut Business and Industry Association, Atlanta Children’s Shelter, SISU Integrated Early Learning, and API Council, discussed the merger’s potential to create an innovative platform that will improve access to high quality and affordable healthcare. In particular, the Asian Business Association and the API Council discussed the potential of the merger to allow for more collaboration between doctors, pharmacists, and insurers, resulting in improved patient care. Commenters, including the Spanish Speaking Elderly Council-RAICES, Inc., the Latino Commission on AIDS, National Hispanic Medical Association, and the National Black Nurses Association, praised CVS for improving public health through removing tobacco from its stores, participating in programs to combat the opioid epidemic, and offering free biometric health screenings. Other commenters such as the Connecticut Business and Industry Association and ValueCare Alliance praised Aetna for providing jobs and collaborating with providers on

⁶⁵ TC-002, TC-004, TC-009, TC-015, TC-020, TC-023, TC-024, TC-026, TC-029, TC-038, TC-044, TC-046, TC-054, TC-056, TC-059, TC-060, TC-061, TC-080, TC-083; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁶⁶ TC-014, TC-023, TC-024, TC-026, TC-027, TC-037, TC-044, TC-046, TC-054, TC-056, TC-057, TC-059, TC-062.

⁶⁷ TC-009, TC-014, TC-015, TC-016, TC-017, TC-020, TC-021, TC-023, TC-024, TC-025, TC-031, TC-033, TC-044, TC-045, TC-047, TC-056, TC-059, TC-060, TC-061, TC-062, TC-063, TC-064, TC-072, TC-074, TC-078, TC-080, TC-081, TC-082, TC-085; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁶⁸ TC-002, TC-003.

⁶⁹ *See also* TC-045.

⁷⁰ TC-002, TC-023, and TC-024.

⁷¹ TC-003, TC-023, TC-024, TC-054, TC-059.

⁷² *See* 15 U.S.C. § 18.

⁷³ TC-001, TC-004, TC-007, TC-011, TC-029, TC-048, TC-060, TC-067, TC-070, TC-078, TC-081; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1. MSSNY further argued that these practices would be driven by the \$40 billion in debt that CVS is incurring as part of the transaction.

⁷⁴ TC-002.

⁷⁵ TC-002, TC-023, and TC-024.

⁷⁶ TC-009, TC-014, TC-015, TC-016, TC-017, TC-020, TC-021, TC-023, TC-024, TC-025, TC-031, TC-033, TC-044, TC-045, TC-047, TC-056, TC-059, TC-060, TC-061, TC-062, TC-063, TC-064, TC-072, TC-074, TC-078, TC-080, TC-081, TC-082, TC-085; *see also* Amicus Brief from the AIDS Healthcare Foundation, Dkt. # 50-1.

⁷⁷ TC-007.

⁷⁸ TC-065.

⁷⁹ TC-005, TC-006, TC-008, TC-010, TC-018, TC-019, TC-022, TC-028, TC-030, TC-036, TC-040, TC-041, TC-042, TC-049, TC-051, TC-052, TC-053, TC-055, TC-058, TC-069, TC-071, TC-073, TC-074, TC-077, TC-079, TC-084.

innovative healthcare products. These comments are consistent with the United States' previous recognition that this merger has the potential to generate benefits by improving the quality and lowering the costs of healthcare services.⁸⁰

VI. Conclusion

After careful consideration of the public comments, the United States continues to believe that the proposed Final Judgment, as drafted, provides an effective and appropriate remedy for the antitrust violations alleged in the Complaint, and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the comments and this response are published as required by 15 U.S.C. § 16(d).

Dated: February 13, 2019
Respectfully submitted,

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[FR Doc. 2019-02846 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-11-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below has applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of schedule I or schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on the previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
Mylan Technologies, Inc.	83 FR 64160	December 13, 2018.
Noramco Inc.	83 FR 64159	December 13, 2018.
Arizona Department of Corrections	83 FR 64364	December 14, 2018.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or schedule II controlled substances to the above listed companies.

Dated: January 29, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02871 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Johnson Matthey, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 25, 2019. Such persons may also file a written request for a hearing on the application on or before March 25, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and

implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on October 12, 2018, Johnson Matthey Inc., 2003 Nolte Drive, West Deptford, New Jersey 08066, applied to be registered as a bulk manufacturer of the following basic classes of controlled substances listed in schedule I & II.

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana	7360	I
Tetrahydrocannabinols.	7370	I
Dihydromorphine	9145	I
Difenoxin	9168	I
Amphetamine	1100	II
Methamphetamine	1105	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II

⁸⁰ See "Justice Department Requires CVS and Aetna to Divest Aetna's Medicare Individual Part D

Prescription Drug Plan Business to Proceed with Merger," available at <https://www.justice.gov/opa/>

[pr/justice-department-requires-cvs-and-aetna-divest-aetna-s-medicare-individual-part-d.](https://www.justice.gov/opa/)

Controlled substance	Drug code	Schedule
Cocaine	9041	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Diphenoxylate	9170	II
Ecgonine	9180	II
Hydrocodone	9193	II
Meperidine	9230	II
Methadone	9250	II
Methadone inter-mediate.	9254	II
Morphine	9300	II
Thebaine	9333	II
Opium tincture	9630	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Alfentanil	9737	II
Remifentanil	9739	II
Sufentanil	9740	II
Tapentadol	9780	II
Fentanyl	9801	II

below. No comments or objections were submitted for this notice.

Company	FR docket	Published
Sigma Aldrich Research.	83 FR 54613	October 30, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a registration as a bulk manufacturer to the above listed company.

Dated: January 29, 2019.

John J. Martin,
Assistant Administrator.
[FR Doc. 2019-02869 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

Company	FR docket	Published
Myoderm	83 FR 66751	December 27, 2018.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrant to import the applicable basic class of schedule II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule II controlled substances to the above listed company.

Dated: February 11, 2019.

John J. Martin,
Assistant Administrator.
[FR Doc. 2019-02870 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

In reference to drug codes 7360 (Marijuana), and 7370 (THC), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

Dated: February 11, 2019.

John J. Martin,
Assistant Administrator.
[FR Doc. 2019-02882 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted a registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on the previous published notice are listed in the table

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and has been granted registration by the Drug Enforcement Administration (DEA) as an importer of schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as an importer of a basic class of controlled substance. Information on the previously published notice is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for this notice.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of schedule I or schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
Janssen Pharmaceuticals, Inc	83 FR 58598	November 20, 2018.
Lipomed	83 FR 58601	November 20, 2018.
Akorn, Inc	83 FR 60896	November 27, 2018.
Cambridge Isotope Laboratories	83 FR 60897	November 27, 2018.
GE Healthcare	83 FR 60899	November 27, 2018.
Fisher Clinical Services, Inc	83 FR 60900	November 27, 2018.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or schedule II controlled substances to the above listed companies.

Dated: January 29, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02866 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 17-01]

Ajay S. Ahuja, M.D.; Decision and Order

On May 25, 2017, Administrative Law Judge (ALJ) Charles Wm. Dorman issued the attached Recommended Decision (R.D.).¹ Neither party filed exceptions to the ALJ's Recommended Decision. Having reviewed the entire record, I have decided to adopt the ALJ's findings of fact as modified,² conclusions of law, and recommended sanction except as explained below.

Respondent's Registration Status

Respondent is the holder of DEA Certificate of Registration AA3029293, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 825 High Ridge Road, Stamford, Connecticut. Government Exhibit (GX) 1, at 1. Although not alleged in the Order to Show Cause, *see* Administrative Law

Judge Exhibit (ALJ Ex.) 1, I also find that the administrative record in this case and this Agency's registration records, of which I take official notice,³ show that Respondent is the holder of DATA-Waiver Identification Number XA3029293. *See* GX 1, at 1.

Respondent's DATA-Waiver authority authorized him to dispense or prescribe schedule III-V narcotic controlled substances which "have been approved by the Food and Drug Administration . . . specifically for use in maintenance or detoxification treatment" for up to 275 patients. 21 CFR 1301.28(a) & (b)(1)(iii).

Respondent's registration was due to expire on June 30, 2017. GX 1, at 1. Although the ALJ correctly indicated that the record before him did "not contain evidence that the Respondent filed an application of renewal," R.D., at 2 n.1, the Agency's registration records do indicate, and I take official notice,⁴ that Respondent submitted a renewal application on May 9, 2017. Because Respondent has submitted a timely renewal application, I find that Respondent's registration has remained in effect pending the issuance of this Decision and Final Order. *See* 5 U.S.C. 558(c); 21 CFR 1301.36(i). Moreover, because Respondent's DATA-Waiver authority is contingent on Respondent being a practitioner with a valid DEA registration, *see* 21 U.S.C. 823(g)(2)(A); 21 CFR 1301.28(a), I find that Respondent's DATA-Waiver authority also remained in effect pending issuance of this Decision and Final Order. Thus, this case remains a live controversy, and I have jurisdiction to decide this matter.

Respondent's Corrective Action Plan

After submitting a timely request for a hearing on October 6, 2016, *see* ALJ Ex. 2, Respondent submitted a Corrective Action Plan (CAP) pursuant to 21 U.S.C. 824(c)(2)(C) on October 25, 2016 to the Deputy Assistant Administrator of DEA's Office of Diversion Control. ALJ Ex. 9. As part of his CAP, Respondent promised that he:

³ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding—even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

⁴ I take official notice of this fact pursuant to the same authority set forth *supra* in footnote 3.

(1) "will not order or dispense controlled substances;" (2) "will no longer prescribe controlled substances to his family members;" (3) "will retain an independent monitor to review and evaluate his practice;" (4) "will continue to educate himself on issues related to drug diversion and enroll in related continuing medical education;" (5) "will cooperate with DEA in a candid and truthful manner in future communications with DEA;" and (6) "will authorize DEA to access all his prescribing records for controlled substances in the Connecticut Prescription Monitoring and Reporting System ('CPMRS')." *Id.* at 2-3.

On November 4, 2016, the Assistant Administrator of DEA's Diversion Control Division rejected Respondent's CAP and further "determined there is no potential modification of your []CAP that could or would alter my decision in this regard." *See* Exhibit A (Letter from then-Assistant Administrator Louis J. Millione to Respondent (dated November 4, 2016)) to ALJ Ex. 11, at 1. I conclude that the facts set forth in the adopted Recommended Decision demonstrate that the Agency had adequate grounds to deny Respondent's CAP. Thus, I agree with the Agency's denial of Respondent's CAP, and I too reject it.

Pre-Hearing Identification of Documents Used To Impeach a Witness on Cross-Examination

In his Recommended Decision, the ALJ criticized the Government's use of the Respondent's earlier deposition testimony⁵ to impeach Respondent during cross-examination because, *inter alia*, "the Government had not identified the deposition transcript as a document it intended to use prior to the hearing." R.D., at 10. I do not adopt the ALJ's suggestion that a party is precluded from using information or a document to impeach a witness during cross-examination unless it is identified prior to the administrative hearing. The APA states that "[a] party is entitled . . . to conduct such cross-examination as may be required for a full and true disclosure of the facts." 5 U.S.C. 556(d). Likewise, Agency precedent has applied this APA standard to hold that ALJs lack the authority to preclude a party from using relevant information to impeach a witness during cross-examination. *See Trinity II*, 83 FR 7304, 7322 n.43 (2018)

⁵ The deposition of Respondent apparently occurred in connection with a civil case brought by the United States Attorney's Office for the District of Connecticut against Respondent. *See* Transcript 61-62, 64, 109-10, 291; *United States v. Ahuja*, No. 3:14-CV-1558, 2017 WL 1807561 (D. Conn. May 5, 2017), *aff'd*, 736 F. App'x 20 (2d Cir. 2018).

¹ All citations to the Recommended Decision are to the slip opinion issued by the ALJ.

² I have modified the Recommended Decision by replacing the full name of DEA and state law enforcement officials with their initials. I have indicated where I have made these modifications in the Recommended Decision with brackets.

(“the CALJ lacks the authority to preclude a respondent from using relevant information to impeach a witness during cross-examination”) (citing 5 U.S.C. 556(d)); *Farmacia Yani*, 80 FR 29053, 29063 n.25 (2015) (finding that it was prejudicial error to preclude a respondent from using a document to impeach a witness on cross-examination, even where respondent had failed to present the document to the Government in advance of the hearing). Thus, all parties have the right to use any relevant information to impeach a witness, regardless of whether the party disclosed that information prior to the administrative hearing.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. AA3029293 and DATA-Waiver Identification Number XA3029293, issued to Ajay S. Ahuja, M.D., be, and they hereby are, revoked. I further order that any pending application of Ajay S. Ahuja to renew or modify the above registration, or any pending application of Ajay S. Ahuja for any other registration, be, and it hereby is, denied. This Order is effective immediately.

Dated: February 10, 2019.

Uttam Dhillon,

Acting Administrator.

Paul A. Dean, Esq., for the Government
Ronald W. Chapman II, Esq., and Robert J. Andertz, Esq., for the Respondent

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Charles Wm. Dorman, Administrative Law Judge.

The Drug Enforcement Administration (“DEA” or “Government”) served Ajay S. Ahuja, M.D., (“Respondent”) with an Order to Show Cause (“OSC”), seeking to revoke his DEA Certificate of Registration (“COR”), Number AA3029293. Administrative Law Judge Exhibit (“ALJ-”) 1. In response to the OSC, the Respondent timely requested a hearing before an Administrative Law Judge. ALJ-2. The hearing in this matter was held in Hartford, Connecticut on March 13, 2017.

The issue before the Administrator is whether the record as a whole establishes that the Respondent’s COR should be revoked and any pending

applications⁶ be denied because the Respondent’s registration would be inconsistent with the public interest under 21 U.S.C. §§ 824(a)(4) and 823(f).

This Recommended Decision is based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

ALLEGATIONS

I. Improper Recordkeeping

1. Between February 2012 and February 2014, the Respondent failed to maintain accurate dispensing records for the following controlled substances, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R. § 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6)⁷:

Alprazolam 1 mg tablets (Schedule IV), Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets (Schedule III), Guaifenesin with Codeine Phosphate 10 mg syrup (Schedule V), Testosterone Cypionate 200 mg/mL injectable (Schedule III), and Zolpidem Tartrate ER 12.5 mg tablets (Schedule IV). ALJ-1, at 2-3.

2. Between February 2012 and February 2014, the Respondent was unable to account for the following controlled substances, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R.

§ 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6): 59 bottles (approximately 5310 tablets) of Alprazolam 1 mg tablets (nearly 10% of total supply), 21 bottles (approximately 630 tablets) of Hydrocodone 10/650 mg tablets (approximately 17.5% of total supply), 58 bottles of Guaifenesin with Codeine Phosphate 10 mg syrup (approximately 27.36% of total supply), 2 vials of Testosterone Cypionate 200 mg/mL injectable (entire supply), and 3 bottles (90 tablets) of Zolpidem Tartrate

⁶ The Respondent’s COR will expire by its terms on June 30, 2017. ALJ-1, at 1. The record does not contain any evidence that the Respondent filed an application for renewal. See 21 C.F.R. § 1301.36(i); *Richard J. Settles, D.O.*, 81 FR 64940, 64940-42, (2016).

⁷ In the OSC and Government’s Prehearing Statement, many of the Government’s citations to the Connecticut statutes and regulations were incorrect. See ALJ-1; ALJ-13, at 12. This issue was addressed during the December 5, 2016 Prehearing Conference, and in my Prehearing Order, issued the same day, and the Government was ordered to prepare copies of the Connecticut statutes and regulations it intended to rely upon. ALJ-20, at 2. In its Supplemental Prehearing Statement, the Government provided an updated list and copies of the correct Connecticut statutes and regulations. ALJ-30, at 12, attach. A. Accordingly, the Respondent was put on notice of the Connecticut statutes and regulations that the Government alleged the Respondent violated. I refer to these updated statutes and regulations in this Recommended Decision.

ER 12.5 mg tablets (entire supply). ALJ-1, at 2-3.

3. Between December 2011 and February 2014, the Respondent failed to maintain a dispensing log in accordance with federal law for the following controlled substances: Alprazolam 1 mg tablets, Hydrocodone 10/650 mg tablets, and Guaifenesin with Codeine Phosphate 10 mg syrup. ALJ-1, at 2-3. Specifically, the Respondent’s dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed, in violation of 21 U.S.C. § 827(a)(3), 21 C.F.R. §§ 1304.22(c), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 2-3.

4. Between February 2012 and January 2014, the Respondent failed to maintain controlled substance receipts for the following orders of controlled substances, in violation of 21 U.S.C. § 842(a)(5), 21 C.F.R. §§ 1304.04(a) and 1304.21(a), Conn. Gen. Stat. § 21a-254(c), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6): 17 shipments of Alprazolam 1 mg tablets, 8 shipments of Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets, 7 shipments of Guaifenesin with Codeine Phosphate 10 mg syrup, a shipment of Testosterone Cypionate 200 mg/mL injectable, and a shipment of Zolpidem Tartrate ER 12.5 mg tablets from A&S Medical Solutions, and 10 shipments of Lyrica 75 mg tablets, and 8 shipments of Lyrica 50 mg tablets from J. Knipper & Company, Inc. ALJ-1, at 3-4.

5. Between December 2011 and February 2014, the Respondent failed to separate his Schedule III-V controlled substance records from his non-controlled substance records, in violation of 21 C.F.R. § 1304.04(f)(2), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4.

6. The Respondent failed to perform and maintain a biennial inventory of controlled substances, in violation of 21 U.S.C. § 827(a)(1), 21 CFR § 1304.11(c), Conn. Gen. Stat. § 21a-254(h), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4.

7. The Respondent failed to report to the Connecticut State Commissioner of Consumer Protection that he was engaging in dispensing drugs, and failed to biennially notify the Commissioner of his intent to continue to dispense drugs, in violation of Conn. Gen. Stat. §§ 20-14f and 21a-317 and 21 C.F.R. § 1306.03(a)(1). ALJ-1, at 5.

II. Improper Prescribing to Himself & Family Members

8. Between 2012 and 2014, the Respondent issued controlled substance prescriptions to himself and his family members for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 5-6.

III. Improper Prescribing to Patients

9. The Respondent issued controlled substance prescriptions to patients for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 6-10.

a. Specifically, on at least 20 occasions between May 2012 and November 2014, the Respondent issued multiple overlapping prescriptions for controlled substances to his patients, which made it possible for these patients to receive early refills of controlled substances and facilitated potential diversion of those controlled substances. ALJ-1, at 6-7.

b. On at least 35 occasions involving at least eight of the Respondent's patients between July 2010 and November 2014, the Respondent issued prescriptions to those patients without any documentation of those prescriptions, or any bases for the prescriptions, in the patient's record, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 7-8.

c. On at least 9 occasions involving at least three of the Respondent's patients between April 2011⁸ and March 2014, the Respondent dispensed controlled substances to those patients from his office supply without any documentation of those dispenses, or any bases for those dispenses, in the patient's records, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. §§ 21a-326-1(c), (d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 8.

⁸Paragraph 9(c) of the OSC lists the inclusive dates as February 2012 and March 2014. ALJ-1 at 8. Subparagraph 9(c)(ii) of the OSC, however, lists the dates as April 2011 and March 2014. ALJ-1, at 8. Further, the Respondent stipulated to the dates of April 2011 and March 2014. ALJ-32, at 6, para. 42. Thus, the Respondent was on notice that the inclusive dates for this allegation were April 2011 and March 2014.

d. On at least 26 occasions involving at least seven of the Respondent's patients between April 2011 and October 2014 the Respondent issued prescriptions to those patients without sufficient documentation of those prescriptions, or any bases for the prescriptions, in the patient's records, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c)(d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 9.

e. On at least 45 occasions involving at least seven patients between May 2010 and March 2014, the Respondent dispensed controlled substance prescriptions from his office supply without sufficient documentation of those dispenses, or sufficient documentation of the bases for them, in the patient's records, in violation of Conn. Gen. Stat. § 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c)(d), and 21 C.F.R. § 1306.04(a). ALJ-1, at 10.

IV. Failure to Maintain Adequate Security

10. The Respondent failed to maintain adequate security for the controlled substances in his possession, in violation of 21 C.F.R. § 1301.75(b) and Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-326-1(d). ALJ-1, at 11.

V. Other Conduct Threatening the Public Health and Safety (Factor Five)

11. Additionally, the Respondent engaged in conduct which may threaten the public health and safety, in violation of 21 U.S.C. C.F.R. § 823(f)(5). ALJ-1, at 11.

WITNESSES

I. The Government's Witnesses

The Government presented its case through the testimony of five witnesses. First, the Government presented the testimony of [R.M.], Director of the Drug Control Division of the State of Connecticut. Tr. 15-32. [R.M.] has held his current position for under a year, and he was previously a Connecticut Drug Control Agent. Tr. 15-16. [R.M.] testified concerning his background, training, and previous experience. Tr. 16. Along with DEA Diversion Investigator [N.C.], [R.M.] was involved in the removal of controlled substances from the Respondent's clinic. Tr. 18. Additionally, [R.M.] testified about the nature and workings of Connecticut's Prescription Monitoring Program ("PMP") and that physicians who dispense controlled substances are required to report that dispensing to the Connecticut PMP. Tr. 17-18. I find [R.M.]'s testimony to be thorough, detailed, and internally consistent.

Therefore, I merit it as credible in this Recommended Decision.

Second, the Government presented the testimony of DEA Diversion Investigator [N.C.]. Tr. 33-48. [N.C.] has been stationed at the DEA Camden Resident Office in Maple Shade, New Jersey since November 28, 2016, but was previously stationed at the DEA Hartford Resident Office in Rocky Hill, Connecticut. Tr. 33-34. [N.C.] testified concerning his background, training, and experience as a diversion investigator for the DEA. Tr. 34. [N.C.] testified that his Group Supervisor, [L.L.], directed him to assist the State of Connecticut in retrieving controlled substances from the Respondent's clinic. Tr. 35. [N.C.] testified that he went with [R.M.] to the Respondent's clinic to pick-up the Respondent's expired controlled substances. Tr. 36-37. I find [N.C.]'s testimony to be thorough and internally consistent. Therefore, I merit [N.C.]'s testimony as credible in this Recommended Decision.

Third, the Government presented the testimony of [P.L.], who was a Drug Control Agent with the Connecticut Department of Consumer Protection. Tr. 49-78. [P.L.] is currently a pharmacist with the Food and Drug Administration, a position she has held since January 2017. Tr. 49. [P.L.] worked with the State of Connecticut Drug Division during the course of the investigation into the Respondent. Tr. 49. [P.L.] testified as to how the investigation into the Respondent began and about how she contacted Diversion Investigator [M.J.] to assist with the investigation. Tr. 51-52. In January 2014, [P.L.] went with [M.J.] to the Respondent's clinic to ask the Respondent some questions. Tr. 55. [P.L.] testified about her interactions with the Respondent during this visit, specifically, statements the Respondent made concerning why the investigators were asking the Respondent about alprazolam, as he did not believe that it was a diverted or abused substance. Tr. 55. [P.L.] and [M.J.] went back to the Respondent's clinic in February 2014 to execute an Administrative Inspection Warrant ("AIW"). Tr. 59. Additionally, [P.L.] testified about the security measures in place for controlled substances at the Respondent's clinic during both of her visits, and how these measures violated Connecticut state regulations. Tr. 64-65. Finally, [P.L.] testified concerning an e-mail correspondence that she had with the Respondent, in which he requested assistance with his expired controlled substances. Tr. 63. I find [P.L.]'s testimony to be thorough, detailed, and internally consistent. Therefore, I merit

it as credible in this Recommended Decision.

Fourth, the Government presented the testimony of DEA Diversion Investigator [M.J.]. Tr. 79-140. [M.J.] testified that she has held her position for six years, and discussed her background and thirteen-week training at the DEA Training Academy at Quantico. Tr. 80. [M.J.] initially became involved in the investigation into the Respondent when she was requested to assist the Connecticut Drug Control Division in their investigation of the Respondent. Tr. 80-81. [M.J.] testified about how she and [P.L.] pulled PMP records for the Respondent. Tr. 81-82.

[M.J.] also testified about her meeting with the Respondent in January 2014 and some of the advisements that she and [P.L.] provided the Respondent with regards to the Respondent's recordkeeping and security practices. Tr. 84-86. Additionally, [M.J.] testified about statements the Respondent made questioning why she and [P.L.] were investigating the Respondent's benzodiazepine prescriptions because he did not believe they were being diverted or abused. Tr. 87. [M.J.] also testified about the events that took place on February 21, 2014, when she, along with [P.L.], another diversion investigator, and two Connecticut police officers, served the Respondent with an AIW. Tr. 94. I find [M.J.]'s testimony to be thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.⁹

Finally, the Government presented the testimony of Adam Perrin, M.D. ("Dr. Perrin"). Tr. 141-209. Dr. Perrin was accepted as an expert, without objection, in the field of clinical medicine in the State of Connecticut with respect to prescribing controlled substances. Tr. 149, 153. Dr. Perrin is currently employed by the University of Connecticut School of Medicine and specializes in family medicine and primary care sports medicine. Tr. 141, 143. He also maintains a medical license in the State of Connecticut, a Certificate of Added Qualification in Primary Care Sports Medicine, a Certificate from the American College of Medical Quality, and is Board Certified in Family Medicine. Tr. 143-44. Additionally, Dr.

⁹ I found [M.J.]'s testimony to be disingenuous concerning her knowledge of the DEA policy concerning the use of DEA Form 82, and whether the form included an advisement to a practitioner of the right to counsel at the time of an inspection. Given her experience and the "hundreds" of times she has used DEA Form 82, that portion of her testimony was not credible. Nevertheless, that testimony concerned only a peripheral issue in this case, and it does not detract from the credibility of the remainder of her testimony. Tr. 112-14, 137-38.

Perrin does team physician work for Wesleyan University, and consulting work for the Livanta Organization, where he conducts peer reviews of cases and determines the appropriateness of a patient's discharge and whether the patient was at the necessary level of care. Tr. 142.

Dr. Perrin testified that he has taken continuing medical education courses in the areas of controlled substances and pain management, most recently through the Connecticut State Medical Society. Tr. 144. He also testified that he has experience treating patients with controlled substances, specifically opiates, dealt with addictive issues of patients, and is familiar with the risks of prescribing controlled substances. Tr. 146-47. He testified that he is familiar with the standards of care in the State of Connecticut and is "familiar with how doctors should conduct themselves in Connecticut while prescribing controlled substances for a legitimate medical purpose." Tr. 148. This body of knowledge is based on Dr. Perrin's experience as a physician and as a teacher of physicians. Tr. 147.

Dr. Perrin testified about Suboxone, what it is and what it is used for. Tr. 153-55. Dr. Perrin reviewed the Ahuja family patient file, Government Exhibit 11, as well as prescriptions written by Dr. Ahuja to his family members to determine whether the records revealed any therapeutic duplication of controlled substances. Tr. 157-59. Additionally, Dr. Perrin reviewed copies of prescriptions written by the Respondent and was asked to compare those prescriptions to the patient files for members of the Respondent's family to determine if the prescriptions were documented in those patient files. Tr. 159-63.

Dr. Perrin reviewed the Stipulations of Fact, ALJ-32, and was asked his opinion with respect to the standard of care. Tr. 164-82. Specifically, Dr. Perrin discussed the potential harm of overlapping prescriptions, Tr. 165, 178, and why having inadequate or no documentation in a patient's file would fall below the standard of care in Connecticut. Tr. 166, 202-04.

I find Dr. Perrin's testimony to be thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.¹⁰

¹⁰ I note that Dr. Perrin mistakenly testified that Suboxone is a Schedule II controlled substance, when it is actually Schedule III. Tr. 154. I also found Dr. Perrin's testimony concerning the reason that he would not write prescriptions for himself or for family members to be less than convincing. Specifically, he testified that there is no law or regulation in Connecticut that prevents a doctor

II. The Respondent's Witness

The Respondent presented his case through his own testimony. Tr. 210-303. The Respondent testified concerning his background, medical education and training. Tr. 211-14. The Respondent also testified as to how he began treating Suboxone patients and the nature of his treatment of these patients. Tr. 216-24. He testified that currently about 80% of his medical practice is devoted to treatment of Suboxone patients. Tr. 217. The Respondent also testified about his treatment of patient D.M., and about a prescription he wrote to this patient for Percocet. Tr. 225-26. Additionally, the Respondent testified about the security measures present in his clinic, including an alarm system, and where he stored his controlled substances. Tr. 227-34. The Respondent also testified as to his interactions with [M.J.] and [P.L.] during their investigation in 2014. Tr. 238, 254-56.

Throughout his testimony on direct examination, the Respondent testified about his changing opinions with regards to what controlled substances are being abused and diverted, Tr. 238-39, and various patient behaviors that present red flags. Tr. 240-42. His opinions changed after he took medical education courses which changed the way he practiced medicine and prescribed controlled substances. Tr. 239-51. The Respondent also testified that during a course he took in January 2017 he learned the importance of documenting the treatment he provided to his patients. Tr. 246.

While the Respondent testified with confidence and clarity during direct examination, his testimony on cross examination was somewhat combative, confusing, and evasive. For example, when the Respondent was asked to compare the content of the OSC with the facts he had stipulated to, he was unable to do so. Tr. 259-63. When the Respondent was asked if his testimony on several issues was different at the hearing than at an earlier deposition, and when showed the transcript of the deposition, the Respondent was unable to recall. Tr. 279-92. When asked twice

from writing a prescription for himself or for family members, but, based on guidance from the American Medical Association ("AMA"), it would be considered an ethical violation to do so. Tr. 194. He further testified that few physicians are aware of the AMA guidelines. Tr. 196-97. He then testified that he would not write such prescriptions because he would be worried about his own license and what his peers might think. Tr. 196, 205. Dr. Perrin finally testified he would not write such prescriptions as a matter of personal philosophy. Tr. 205-06. These two minor areas of Dr. Perrin's testimony, do not undermine my assessment that, overall, his testimony is credible and merits significant weight.

when his office associate, Dr. Jacobson, left the Respondent's medical practice, the Respondent gave rambling answers, but he did not answer the question of when Dr. Jacobson left. In addition, when badgered as to the number of Suboxone patients that he treats, the Respondent eventually did not even give an approximate number. Tr. 275-79.

While combativeness, confusion and evasiveness tend to undermine the credibility of a witness, here the combativeness, confusion and evasiveness concerned issues of little significance. For example, having the Respondent agree that the factual allegations contained in the OSC matched many of the facts to which the Respondent had already stipulated was meaningless. The two documents speak for themselves. Further, the Government's use of the Respondent's earlier deposition testimony was a meaningless exercise for several reasons. First, the Government had not identified the deposition transcript as a document it intended to use prior to the hearing. Second, the issues the Government questioned the Respondent about, based upon his deposition testimony, do not relate to the allegations contained in the OSC, except for the disposition of some cough syrup, where the Respondent admitted he took some home. Tr. 291, 298. Third, it had minimal impeachment value. Finally, as the Respondent noted, the exact number of Suboxone patients the Respondent treats, so long as it is less than the number he is allowed to treat, is of no consequence to this decision. Accordingly, when accessing the Respondent's credibility, I find that the clear and confident manner in which the Respondent testified on direct examination outweighs the manner in which he testified on cross examination. Further, when comparing his testimony to that of other witnesses, I find that it was generally consistent with that of the Government's witnesses. Thus, I find the Respondent's testimony credible on all relevant factual issues. I, however, find it less credible than that of other witnesses in one area.

The Respondent testified that he did not recall telling [M.J.] and [P.L.] that benzodiazepines are not commonly diverted or abused. Tr. 282. [P.L.] testified that the Respondent did not understand why she was concerned about alprazolam, which is a benzodiazepine, because he did not think it was diverted or abused. Tr. 55. [M.J.] also testified that she heard the Respondent make a similar statement. Tr. 87. The Respondent testified that he told [M.J.] and [P.L.] that oxycodone

was more addictive than a benzodiazepine. Tr. 253, 282. Given the Respondent's acknowledgement of discussing the topic and his inability to recall if he made the statement reported by both [M.J.] and [P.L.], I credit their testimonies on this issue.

The parties stipulated to the authenticity of all of the Government's exhibits, accordingly, all of the Government's exhibits were admitted into evidence. Tr. 8. Additionally, the parties stipulated to the authenticity of Respondent Exhibits A, C-J, accordingly, these exhibits were also entered into evidence. Tr. 9.

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

STIPULATIONS OF FACT ¹¹

The Government and the Respondent stipulated the following facts ("Stip. of Fact"):

1. Respondent is registered with the DEA as a practitioner to handle Controlled Substances in Schedules II-V under DEA COR AA3029293 at 825 High Ridge Road, Stamford, Connecticut 06905-1904.

2. Respondent is presently licensed in Connecticut as a medical doctor (M.D.) with medical license 25539.

3. On February 21, 2014, DEA executed an Administrative Inspection Warrant at Respondent's medical practice. During the execution of the warrant, DEA and state drug control agents reviewed documentation of Respondent's recordkeeping practices related to his obligations under the Controlled Substances Act (CSA), its regulations, and state law.

Recordkeeping Violations

4. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Alprazolam 1 mg tablets, a Schedule IV controlled substance, and was unable to account for 59 bottles (approximately 5310 tablets) of Alprazolam 1 mg tablets received from his supplier.

5. Between February 2012 and February 2014, Respondent failed to maintain a dispensing log for Alprazolam 1 mg tablets in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written

initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

6. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Hydrocodone Bitartrate with Acetaminophen 10/650 mg (Hydrocodone 10/650 mg) tablets, a Schedule III controlled substance, and was unable to account for 21 bottles (approximately 630 tablets) of Hydrocodone 10/650 mg tablets received from his supplier.

7. Between January 2012 and February 2014, Respondent failed to maintain a dispensing log for Hydrocodone 10/650 mg tablets in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

8. Between February 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Guaifenesin with Codeine Phosphate 10 mg syrup, a Schedule V controlled substance, and was unable to account for 58 bottles of Guaifenesin with Codeine Phosphate 10 mg syrup received from his supplier.

9. Between December 2011 and February 2014, Respondent failed to maintain a dispensing log for Guaifenesin with Codeine Phosphate 10 mg syrup in accordance with federal law. In particular, Respondent's dispensing records did not include the typewritten or written initials of the dispensing physician and/or the address of the person to whom the medication was dispensed.

10. Between May 2012 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Testosterone Cypionate 200 mg/mL injectable, a Schedule III Controlled Substance and was unable to account for 2 vials of Testosterone Cypionate 200 mg/mL injectable received from his supplier.

11. Between August 2013 and February 2014, Respondent failed to maintain accurate dispensing records for his dispensation of Zolpidem Tartrate ER 12.5 mg tablets, a Schedule IV controlled substance, and was unable to account for 3 bottles (90 tablets) of Zolpidem Tartrate ER 12.5 mg tablets received from his supplier.

12. Between February 2012 and November 2013, Respondent ordered 17 shipments of Alprazolam 1 mg tablets from A&S Medical Solutions. Respondent failed to maintain

¹¹ These stipulations of fact are numbered the same manner as those found in ALJ-32, and also correspond to the references made to a specific stipulation mentioned in the transcript.

controlled substance receipt records for any of these shipments.

13. Between February 2012 and November 2013, Respondent ordered 8 shipments of Hydrocodone Bitartrate with Acetaminophen 10/650 mg tablets from A&S Medical Solutions.

Respondent failed to maintain controlled substance receipt records for any of these shipments.

14. Between February 2012 and November 2013, Respondent ordered 7 shipments of Guaifenesin with Codeine Phosphate 10 mg syrup from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for any of these shipments.

15. Between February 2012 and January 2014, Respondent ordered a shipment of Testosterone Cypionate 200 mg/mL injectable from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for this shipment.

16. Between February 2012 and January 2014, Respondent ordered a shipment of Zolpidem Tartrate ER 12.5 mg tablets from A&S Medical Solutions. Respondent failed to maintain controlled substance receipt records for this shipment.

17. Between February 2012 and January 2014, Respondent ordered 10 shipments of Lyrica 75 mg tablets, a Schedule V controlled substance, from J. Knipper & Company, Inc. Respondent failed to maintain controlled substance receipt records for these shipments.

18. Between February 2012 and January 2014, Respondent ordered 8 shipments of Lyrica 50 mg tablets, a Schedule V controlled substance, from J. Knipper & Company, Inc. Respondent failed to maintain controlled substance receipt records for these shipments.

19. Between December 2011 and February 2014, Respondent failed to separate Schedule III–V controlled substance records from his non-controlled substance records. Specifically, Respondent's Schedule III–V dispensing logs included dispensing logs for Azithromycin, which is not a controlled substance.

20. Respondent failed to perform and maintain a biennial inventory of controlled substances.

21. Respondent failed to report to the State Commissioner of Consumer Protection that he was engaged in dispensing drugs, and Respondent failed to biennially notify the Commissioner of his intent to continue to dispense drugs.

Improper Prescribing to Family Members

22. After the execution of the administrative warrant, DEA issued

Respondent two successive administrative subpoenas for copies of patient records for several individuals to whom Respondent had issued controlled substances prescriptions, including Respondent and several family members.

23. On December 18, 2014, pursuant to an administrative subpoena, Respondent provided DEA with a copy of, among others, patient records for himself and certain family members, including N.A., U.A., and G.A.

24. On at least two occasions between December 2012 and December 2014, Respondent either issued, or dispensed, overlapping prescriptions of controlled substances constituting early fills for himself (alprazolam 1 mg, Schedule IV) and a family member, N.A., (zolpidem tartrate 10 mg).

25. On at least seven additional occasions, between February and September 2014, Respondent either issued a controlled substance prescription to himself (lorazepam, Schedule IV) or dispensed controlled substances to himself (guaifenesin with codeine, Schedule V; alprazolam 1 mg, Schedule IV) with inadequate documentation in the medical record.

26. On at least five additional occasions, between February and October 2014, Respondent issued his family member, N.A., prescriptions for a variety of controlled substances (including Lunesta 3 mg, Schedule IV; zolpidem tartrate 10 mg, Schedule IV; alprazolam 1 mg, Schedule IV) with inadequate documentation in the medical record.

27. On at least one additional occasion, between April and December 2014, Respondent issued a controlled substance prescription (hydrocodone 10 mg/acetaminophen 650 mg (Lorcet), formerly Schedule III) to family member, G.A., and inadequately documented that prescription and the basis for it in G.A.'s medical record.

Improper Prescribing to Patients

28. On December 18, 2014 and July 31, 2015, pursuant to DEA administrative subpoenas, Respondent provided DEA with a copy of patient records for certain patients, including J.C., J.Cu., W.L., L.M., R.P., M.R., A.S., J.T., and J.V.

29. On ten occasions between May and November 2012, Respondent issued multiple overlapping prescriptions for alprazolam 1 mg (Schedule IV) to his patient, J.Cu., within days of issuing previous prescriptions to J.Cu. for the same controlled substance. For example, in the course of 199 days in which, by Respondent's instructions, J.Cu. should not have consumed more than 597

dosage units of Alprazolam 1 mg, Respondent prescribed J.Cu. 1870 dosage units of Alprazolam 1 mg.

30. On five occasions between October and November 2014, Respondent issued multiple overlapping prescriptions for controlled substances (Tramadol 50 mg (Schedule IV), Methylphenidate 20 mg (Schedule II), and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient, J.T., within days of issuing previous prescriptions to J.T. for the same controlled substances. In the course of 28 days in which, by Respondent's limited instructions, J.T. should not have consumed more than 84 dosage units of Tramadol 50 mg, Respondent prescribed or dispensed to J.T. 540 dosage units of Tramadol. Likewise, Respondent issued J.T. a prescription for 90 tablets of Methylphenidate 20 mg for a thirty day supply. Six days later Respondent issued J.T. two additional prescriptions for a total of 90 additional tablets of Methylphenidate. On November 15, 2014, Respondent issued J.T. a prescription for 30 tablets of Dextroamphetamine/Amphetamine 20 mg, a 15 day supply. Three days later, Respondent issued J.T. another prescription for 45 additional tablets of the same controlled substance.

31. On four occasions between June and October 2012, Respondent issued multiple overlapping prescriptions for alprazolam 1 mg to his patient, A.S., within days of issuing a previous prescription to A.S. for the same controlled substance. In the course of 133 days in which, by Respondent's limited instructions, A.S. should not have consumed more than 399 dosage units of Alprazolam 1 mg, Respondent prescribed or dispensed to A.S. at least 780 dosage units of Alprazolam 1 mg.

32. On one occasion in October 2012, Respondent issued an overlapping prescription for alprazolam 1 mg (Schedule IV) to his patient, M.R., within days of issuing a previous prescription to M.R. for the same controlled substance. In the course of 28 days in which, by Respondent's instructions, M.R. should have consumed 42 dosage units of Alprazolam 1 mg, Respondent prescribed M.R. 150 dosage units of Alprazolam 1 mg during that time frame.

33. On eight occasions between October and November 2014, Respondent issued controlled substance prescriptions (including Tramadol 50 mg (Schedule IV), methylphenidate 20 mg (Schedule II), and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient J.T. without any documentation of those

prescriptions, or the bases for them, in the patient's medical record.

34. On seven occasions between July 2010 and July 2014, Respondent issued controlled substance prescriptions (Diazepam 5 and 10 mg (Schedule IV)) to his patient L.M. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

35. On six occasions between May 2012 and March 2013, Respondent issued controlled substance prescriptions (including dextroamphetamine/amphetamine 20 mg and alprazolam 1 mg) to his patient W.L. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

36. On four occasions between May 2012 and February 2013, Respondent issued controlled substance prescriptions (including alprazolam 1 mg and phenobarbital 60 mg—both Schedule IV) to his patient J.Cu. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

37. On four occasions between May 2011 and November 2013, Respondent issued controlled substance prescriptions (Hydrocodone 7.5 mg/Ibuprofen 200 mg (Schedule III)) to his patient R.P. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

38. On four occasions between November 2011 and March 2014, Respondent issued controlled substance prescriptions (alprazolam 1 mg (Schedule IV) and Oxycodone 10 mg/Acetaminophen 325 mg (Schedule III)) to his patient M.R. without any documentation of those prescriptions, or the bases for them, in the patient's medical record.

39. On at least one occasion in December 2013, Respondent issued a prescription for alprazolam 1 mg (Schedule IV) to his patient J.C. without any documentation of that prescription, or the basis for it, in the patient's medical record.

40. On at least one occasion in October 2012, Respondent issued a prescription for alprazolam 1 mg (Schedule IV) to his patient A.S. without any documentation of that prescription, or the basis for it, in the patient's medical record.

41. On five occasions between June 2012 and April 2013, Respondent dispensed controlled substances (alprazolam 1 mg (Schedule IV) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient A.S. without any documentation of those dispenses, or

their bases, in the patient's medical record.

42. On two occasions between April 2011 and March 2014, Respondent dispensed controlled substances (alprazolam 1 mg (Schedule IV) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient W.L. without any documentation of those dispenses, or their bases, in the patient's medical record.

43. On two occasions between February 2012 and October 2012, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient J.V. without any documentation of those dispenses, or their bases, in the patient's medical record.

44. On ten occasions between September 2013 and March 2014, Respondent issued controlled substance prescriptions (dextroamphetamine/amphetamine 20 mg and 30 mg (Schedule II) and alprazolam 1 mg (Schedule IV)) to his patient J.C. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

45. On six occasions between April 2011 and March 2014, Respondent issued controlled substance prescriptions (dextroamphetamine/amphetamine 20 mg) to his patient W.L. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

46. On at least two occasions between May 2012 and February 2013, Respondent issued controlled substance prescriptions (phenobarbital 60 mg (Schedule IV) and alprazolam 1 mg (Schedule IV)) to his patient J.Cu. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

47. On at least two occasions between February 2013 and July 2013, Respondent issued controlled substance prescriptions (diazepam 10 mg (Schedule IV)) to his patient L.M. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

48. On at least two occasions between April 2012 and October 2012, Respondent issued controlled substance prescriptions (hydrocodone 10 mg/acetaminophen 325 mg (Schedule III)) and on at least two occasions between April 2012 and October 2012, Respondent issued controlled substance prescriptions (hydrocodone 7.5 mg/ibuprofen 200 mg (Schedule III) and hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) to his patient R.P. with insufficient documentation of

those prescriptions, or the bases for them, in the patient's medical record.

49. On at least two occasions between May 2012 and October 2012, Respondent issued controlled substance prescriptions (oxycodone 7.5 mg/ibuprofen 200 mg (Schedule III) and alprazolam 1 mg (Schedule IV)) to his patient M.R. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

50. On two occasions in October 2014, Respondent issued controlled substance prescriptions (methylphenidate 20 mg (Schedule II) and dextroamphetamine/amphetamine 20 mg (Schedule II)) to his patient J.T. with insufficient documentation of those prescriptions, or the bases for them, in the patient's medical record.

51. On 12 occasions between May and November 2012, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III) and alprazolam 1 mg (Schedule IV)) from his office supply to his patient J.Cu. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

52. On 12 occasions between May 2010 and July 2013, Respondent dispensed a controlled substance (hydrocodone 10 mg/acetaminophen 650 mg (Schedule III)) from his office supply to his patient J.V. with insufficient documentation of those dispenses, or the bases for them, in the patient's record.

53. On nine occasions between May 2011 and November 2013, Respondent dispensed controlled substances (hydrocodone 7.5 mg/ibuprofen 200 mg (Schedule III), hydrocodone 7.5 mg/acetaminophen 650 mg, and guaifenesin with codeine (Schedule V)) from his office supply to his patient R.P. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

54. On seven occasions between April 2011 and July 2013, Respondent dispensed controlled substances (hydrocodone 10 mg/acetaminophen 650 mg and alprazolam 1 mg) from his office supply to his patient W.L. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

55. On two occasions between June 2013 and March 2014, Respondent dispensed a controlled substance (alprazolam 1 mg (Schedule IV)) from his office supply to his patient M.R. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

56. On at least two occasions between October 2012 and April 2013,

Respondent dispensed a controlled substance (alprazolam 1 mg) from his office supply to his patient A.S. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

57. On at least one occasion between September 2013 and March 2014, Respondent dispensed a controlled substance (alprazolam 1 mg (Schedule IV)) from his office supply to his patient J.C. with insufficient documentation of those dispenses, or the bases for them, in the patient's medical record.

Accordingly, the Respondent stipulated to a majority of the facts alleged by the Government in the OSC. However, the Respondent did not stipulate to the factual allegations: concerning prescribing to himself and his family members; concerning his failure to maintain adequate security; and concerning his other conduct which may have threatened the public health and safety.

FINDINGS OF FACT¹²

I. Respondent's Background

1. The Respondent was born and raised in New Delhi, India. Tr. 211. As a child, the Respondent spoke Hindi, Punjabi, and a little English at home with his family. Tr. 211.

2. The Respondent earned his college degree in 1971 from the College of Sciences in New Delhi. Tr. 211. Subsequently, the Respondent went to medical school at the Maulana Azad Medical College in New Delhi, and graduated in 1977. Tr. 211-12.

3. In April of 1979, the Respondent came to the United States. Tr. 212.

4. Once in the United States, the Respondent took a three-month course to prepare to take the Educational Commission for Foreign Medical Graduates exam, to have his medical degree recognized in the United States. Tr. 212. The Respondent passed this exam in July of 1979. Tr. 213.

5. In July 1980, the Respondent began an internship at LaGuardia Hospital in Forest Hills, New York. Tr. 213.

6. After his internship, the Respondent finished his residency at Andover Hospital in 1984. Tr. 213. The Respondent specialized in internal medicine. Tr. 213.

7. The Respondent was licensed to practice medicine in the State of Connecticut in January 1985. Tr. 214.

8. After being licensed, the Respondent worked at a "walk-in" medical clinic in Danbury, Connecticut. Tr. 214.

9. In 1988, the Respondent opened the Immediate Medical Care Center, which he still owns and where he maintains his medical practice. Tr. 215.

II. The 2014 Investigation

10. [P.L.] began investigating the Respondent after she received information from a probation officer who had concerns about the Respondent's prescribing habits. Tr. 51. [P.L.] ran a report using Connecticut's prescription monitoring and reporting system ("PMP") to review the Respondent's prescribing habits and she identified prescriptions suggestive of "early refills or duplicate therapy." Tr. 51. [P.L.] also contacted the DEA, [M.J.], because of the controlled substances involved. Tr. 52, 81. At this point, it was a joint investigation between the DEA and the State of Connecticut. Tr. 52-53.

11. Pharmacies in Connecticut are required to submit information into the PMP when they fill a prescription. Tr. 73. In addition, when a doctor dispenses a controlled substance, the doctor is required to report that event to the PMP within 24 hours. Tr. 18, 30-31. When [P.L.] ran the Respondent's PMP, it should have shown "all prescriptions that have been filled by pharmacies uploaded into the PMP under [the Respondent] as the prescriber," as well as any controlled substances the Respondent had dispensed and reported. Tr. 73-74. Administering a controlled substance directly to the patient would not show up on the PMP, but dispensing the substance to the patient to take home would show up on the PMP—if properly reported. Tr. 75-76.

12. [P.L.] and [M.J.] went through the Respondent's PMP report and then collected copies of prescriptions the Respondent had written from the pharmacies that filled the prescriptions. Tr. 51, 54, 62-63.

13. [M.J.] also pulled data from the Automation of Reports and Consolidated Orders System ("ARCOS"). Tr. 83. ARCOS is a DEA system where manufacturers and distributors report purchases of specific controlled substances by a registrant. Tr. 83-84.

14. Although the ARCOS records indicated that the Respondent had obtained controlled substances, the PMP report did not indicate that he had dispensed any. Tr. 81, 139.

15. On the morning of January 31, 2014, [M.J.] and [P.L.] arrived, unannounced, at the Respondent's

clinic to speak with him. Tr. 55-56, 83, 117. When they arrived, the only other employee at the Respondent's clinic was his secretary. Tr. 77. Because the Respondent was busy with patients, he asked [M.J.] and [P.L.] if they could talk later that day when another physician would be in the office to see patients. Tr. 55, 117, 254-55. When [M.J.] and [P.L.] came back later in the day on January 31, 2014, another physician was present. Tr. 78.

16. When [P.L.] and [M.J.] returned to the Respondent's office on January 31, 2014, they asked the Respondent if he prescribed to his family members. Tr. 55, 86. The Respondent indicated he mostly did not, "because he did not want to take the responsibility if something went wrong." Tr. 55-56; *see also* Tr. 70, 87. When [P.L.] showed the Respondent the prescriptions written for family members, the Respondent verified that he wrote the prescriptions. Tr. 56. When [M.J.] and [P.L.] asked the Respondent if he had copies of patient files for his family members the Respondent said he did not. Tr. 56, 87.

17. On January 31, 2014, [M.J.] and [P.L.] advised the Respondent of the requirement to conduct a biennial inventory and about the security of controlled substances. Tr. 84-85, 118.

18. On January 31, 2014, [M.J.] and [P.L.] asked the Respondent to sign an agreement stating that he would no longer treat his family members, but he refused to do so. Tr. 56.

19. The Respondent refused to allow [M.J.] and [P.L.] to conduct an audit of the controlled substances he had in his clinic on January 31, 2014, and he denied their request to conduct an inspection. Tr. 56, 87, 93-94, 117.

20. On January 31, 2014, the Respondent told [M.J.] and [P.L.] that he was not aware that alprazolam, a benzodiazepine, was being abused or diverted. Tr. 55, 87; *see also* Tr. 238, 253, 268-69.

21. On February 21, 2014, [M.J.], [P.L.], DI [J.H.], and two Stanford police officers, arrived at the Respondent's clinic to execute an Administrative Investigation Warrant ("AIW") in order to collect records and to perform a count of the Respondent's controlled substances. Tr. 59-60, 94.

22. [M.J.] served the Respondent with the warrant on February 21, 2014, and he was not cooperative initially. Tr. 60, 94-95. [J.H.], one of the police officers, and the Respondent's secretary, encouraged the Respondent to comply with the warrant. Tr. 60, 94-95.

23. On February 21, 2014, [M.J.] attempted to conduct an audit of the Respondent's controlled substances, but was unable to do so because there was

¹² The extensive and detailed stipulations of fact essentially establish the factual bases for most of the allegations contained in the OSC. It is, therefore, unnecessary to make additional findings of fact based upon my independent review of documentary evidence and my evaluation of the credible testimony, where those findings would essentially duplicate the stipulations of fact.

no biennial inventory. Tr. 96. Instead, [M.J.] performed a closing count and the investigators collected what records they were able to from the Respondent, including some dispensing logs and what the Respondent called his medication log. Tr. 96-97.

III. Recordkeeping & PMP Requirements

24. There were recordkeeping issues in the Respondent's practice prior to February 2014. Tr. 224.

25. After reviewing the documents that [M.J.] and [P.L.] were able to obtain during the execution of the AIW on February 21, 2014, they were able to identify some problem patients, review their data, and request their records. Tr. 102-03.

26. Prior to April 2014, the Respondent had never logged onto the PMP system. Tr. 102. Although there is nothing in the Code of Federal Regulations ("CFR") that specifically requires a physician to check the PMP records, Tr. 103, federal law requires a practitioner to comply with state law.¹³ Tr. 103.

27. In Connecticut, a practitioner is required to notify the state of his intent to dispense controlled substances. Conn. Gen. Stat. § 20-14f; Tr. 19.

28. After the Respondent stopped dispensing controlled substances, he no longer had an obligation to report that he intended to dispense controlled substances. Tr. 25.

29. Respondent Exhibit D is a "Record of Surrender or Disposal" issued by the State of Connecticut—Department of Consumer Protection, Drug Control Division. RE-D. The record is signed by the Respondent, [R.M.], and [N.C.], and it documents the controlled substances that were received from the Respondent's clinic on March 4, 2016. Tr. 21, 40; RE-D.

30. Even if the Respondent is no longer dispensing controlled substances, it would still be considered a state violation in 2017 if the Respondent failed to report dispensing controlled substance to the state that occurred in 2014. Tr. 29.

IV. Security

31. The purpose of requiring that a storage cabinet be substantially secure is

¹³ In determining whether the continued registration is in the public interest, federal law requires the consideration of the respondent's compliance with applicable state, federal, or local laws related to controlled substances. 21 U.S.C. § 823(f)(4) ("Factor Four"). The DEA has found that a respondent's failure to report various dispensings to the state's PMP, in violation of that state's law, was a violation under Factor Four. See *Keith Ky Ly, D.O.*, 80 Fed. Reg. 29025, 29035 (2015).

to prevent the theft or diversion of controlled substances. Tr. 123.

32. The Respondent stored all of his controlled and non-controlled substances in the same location.¹⁴ Tr. 57.

33. Prior to [M.J.] and [P.L.]'s arrival at the Respondent's office on January 31, 2014, the Respondent kept his controlled substances in an unlocked closet, with a louvered door, located in a locked unused patient care room. Tr. 57-58, 65-66, 85-86, 229, 232, 301-03.

34. The Respondent stored unused medical equipment, valued at approximately \$150,000, in the unused locked examination room, where he also stored his controlled substances. Tr. 229-30.

35. On February 21, 2014, the controlled substances were in the same unlocked closet as they were when [M.J.] and [P.L.] visited the Respondent on January 31, 2014. Tr. 60-61, 95, 232.

36. The Respondent did not order any additional controlled substances after the investigators came to visit him. Tr. 231.

37. The Respondent "set up a lock in the closet" because the investigators asked him to do so. Tr. 231-32; *see also* Tr. 36, 40.

38. When [R.M.] came to the Respondent's clinic on March 4, 2016, he does not remember if the Respondent's controlled substances were locked in a cabinet. Tr. 22.

39. When [R.M.] and [N.C.] arrived at the Respondent's clinic on March 4, 2016, to retrieve the Respondent's expired controlled substances, the closet where the controlled substances were stored was not locked. Tr. 36-37, 41. The door to the unused examination room was closed, but [N.C.] does not recall if it was locked. Tr. 42, 46-47.

40. The Respondent denies that he failed to maintain adequate security of the controlled substances in his possession. Tr. 268; 301.

V. Prescribing to Self and Family

41. Concerning the allegation of therapeutic duplication, the Respondent knew that the patient would not take the two medications at the same time because the patient was his own son, N.A. Tr. 266-67. N.A. came to the Respondent and told him that the medication he was currently taking was not working and asked the Respondent

¹⁴ At the hearing, [P.L.] testified that storing controlled and non-controlled substances in the same location was a separate violation of regulations. Tr. 57. This allegation, however, was never raised in the OSC or in any of the Government's prehearing or post-hearing filings. See ALJ-1; ALJ-13; ALJ-30. Therefore, I give no weight to this testimony.

if he could prescribe something else. Tr. 267. N.A. lived with the Respondent. Tr. 267.

42. The Respondent wrote prescriptions for controlled substances to either himself or to family members, N.A. or U.A., at least 14 times between June 2012 and December 2014 without any documentation of those prescriptions or any bases for those prescriptions in any medical records. Tr. 56, 87, 161-63, 267-68; GE-11, GE-13-23, GE-25-31.

43. Government Exhibit 8 is a prescription for Percocet written by the Respondent to patient D.M. on November 23, 2013. Tr. 92, 225; GE-8. D.M. is the Respondent's patient. Tr. 225. When the pharmacy filled this prescription, it was issued to the Respondent, rather than to D.M. Tr. 92; GE-8.

44. D.M.'s patient file does not contain an entry on November 23, 2013. Tr. 93.

45. The prescription written to D.M. is for Percocet, which contains oxycodone. Tr. 226; GE-8. The Respondent cannot take oxycodone. Tr. 226-27.

VI. Dr. Perrin's Testimony

46. Physicians who write prescriptions and dispense controlled substances in Connecticut are subject to regulatory review. Tr. 153.

47. Dr. Perrin's testimony regarding inadequate documentation was based on his review of the patient files of the Respondent's patients, to include those of the Respondent's family. Tr. 156, 201-02.

48. Suboxone is a synthetic opioid-based medication that is primarily used to treat patients who are addicted to opioids. Tr. 154, 198.¹⁵

49. Alprazolam is a Schedule IV controlled substance and is classified as a benzodiazepine. Tr. 154.

50. According to Centers for Disease Control and Prevention guidance, prescribing opioids and benzodiazepines in conjunction with each other "should be avoided because the combination can be potentially very dangerous in terms of overdose and addictive potential." Tr. 155. The rationale being that "[w]hen you combine those two substances, they can be significantly over-sedating" and put the patient at a "higher risk for overdose." Tr. 199.

51. Government Exhibit 18 is a prescription for Lunesta, indicating five refills, issued by the Respondent to N.A.

¹⁵ Although Dr. Perrin testified that Suboxone is a Schedule II substance, Tr. 154, it is in fact listed in Schedule III. 21 C.F.R. § 1308.13(e)(2)(i).

on February 24, 2014. GE-18; Tr. 157. Lunesta is a sedative hypnotic agent that is used to treat insomnia. Tr. 156-57.

52. Government Exhibit 19 is a prescription for Ambien, with five refills, issued by the Respondent to N.A. on March 5, 2014. GE-19; Tr. 157. Ambien is also a sedative hypnotic used to treat insomnia. Tr. 156-57.

53. Government Exhibit 19 is an overlapping prescription with Government Exhibit 18. Tr. 157.

54. The combination of prescriptions Lunesta and Ambien constitutes therapeutic duplication. Tr. 157.

55. In the Respondent's patient file for N.A., there is a notation, dated March 5, 2014, that "Lunesta doesn't help changed to Ambien 10 mg #30." GE-11, at 7. In Dr. Perrin's opinion, this notation is not sufficient to justify the therapeutic duplication. Tr. 158-59. Therapeutic duplication can be dangerous if one prescription is not discontinued in favor of the other. Tr. 159. Dr. Perrin explained that "[i]t has to be carefully explained not to mix" and that "[i]deally we like to dispose of the prior prescription" and have that noted in the patient file. Tr. 159.

56. The Respondent's practice of issuing overlapping prescriptions of controlled substances for himself, a family member, and other patients fell below the standard of care in Connecticut. Tr. 164-65, 169-73, 203-04; Stip. of Fact 24, 29-32. Issuing "overlapping prescriptions . . . could pose potential harm if taken simultaneously for . . . those who don't know to take it properly." Tr. 165. Additionally, "it's a cumulative effect of too much of a potentially sedating medication that also has addictive potential." Tr. 165.

57. Overlapping prescriptions increase the potential for diversion because of the additional controlled substances floating around. Tr. 207.

58. Issuing early refills is not a legitimate medical practice in the State of Connecticut. Tr. 165.

59. There is no law or regulation in the State of Connecticut that prohibits a doctor from self-prescribing. Tr. 194, 206. According to the American Medical Association ("AMA"), however, it is considered an "ethical violation" to self-prescribe controlled substances. Tr. 166, 194. The AMA ethical rules do not automatically set the standard of care. Tr. 194. Additionally, there are exceptions in the AMA rule to self-prescribing, including short-term treatment or minor problems. Tr. 195.

60. The Respondent's practice of issuing a controlled substance prescription to himself or his family members, or dispensing a controlled

substance to himself or his family members, however, without adequate documentation in the medical record is below the standard of care in the State of Connecticut. Stip. of Fact 25-27; Tr. 166. With any prescription of a controlled substance, it is "important to provide adequate documentation as to the precise reason for why [the] particular substance is indicated." Tr. 166. There needs to be "an appropriate diagnosis that underlies the prescribing of said substance, and [there] has to be documentation that's beyond cursory to substantiate the choice of prescribing said substance." Tr. 166.

61. Where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance there is no legitimate medical purpose for the prescription.¹⁶ Tr. 202. Thus, the Respondent's practice of issuing controlled substance prescriptions or dispensing controlled substances from his office supply, to patients without adequate documentation, or bases for the prescription or dispensing in the patient's medical record fell below the standard of care in the State of Connecticut and were not issued or dispensed for a legitimate medical purpose. Tr. 167-69, 173, 179-81; Stip. of Fact 25-27, 33-57.

VII. Acceptance of Responsibility

62. The Respondent admitted to most of the factual allegations contained in the COR, but he refused to answer the questions regarding whether his actions were either below the standard of care or outside the course of professional practice. Tr. 264-66; *see also* Stip. of Fact 4-57.

63. The Respondent denied that he had issued overlapping prescriptions to N.A. in a manner that constituted therapeutic duplication. Tr. 267.

64. The Respondent denied that he failed to maintain adequate security of his controlled substances, as alleged in paragraph 10 of the OSC. Tr. 268. The Respondent admitted to most of factual allegations contained in paragraph 10 of the OSC, but he denies that the room where the controlled substances were kept in an unlocked closet was unlocked. Tr. 302-03.

65. The Respondent denies that he made any statement suggesting that his "dispensing of 'benzos' was not worthy of DEA investigation, particularly given how other doctors in [his] community

were distributing Schedule II controlled substances," as alleged in paragraph 11(a) of the OCS. ALJ-1, at 11; Tr. 268-69.

66. The Respondent denies the allegations contained in paragraph 11(b) of the OSC, alleging that he attempted to mislead the DEA during its investigation. Tr. 269.

Additional facts required to resolve the issues in this case are included in the Analysis section of this Recommended Decision.

ANALYSIS

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman v. SEC*, 450 U.S. 91, 100-02 (1981); 21 C.F.R. § 1301.44(e). Under 21 U.S.C. § 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration "inconsistent with the public interest." The DEA considers the following five factors to determine whether continued registration is in the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. § 823(f) (2012).

These public interest factors are considered separately. *See Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76-77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.*, 74 FR 10083 (2009).

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the

¹⁶ While Dr. Perrin's testimony on this issue focused on Stip. of Fact 30, I find the reasoning applicable to situations where there is inadequate documentation of the need to prescribe a controlled substance.

evidence. *Steadman*, 450 U.S. at 100-03. If the Government presents a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate. *Med. Shoppe-Jonesborough*, 73 FR 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.*, 75 FR 8194, 8236 (2010). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.*, 78 FR 38363, 38385 (2013).

I. The Government's Position

Here, the Government seeks to revoke the Respondent's COR based on Factors Two, Four, and Five. Post-Hearing Brief on Behalf of the Government ("Gov't Brief").¹⁷ ALJ-37 at 19-22. With regard to Factors Two and Four, the Government argues that the Respondent's "repeated failure to comply with Federal and State laws relating to the prescribing, dispensing, and recordkeeping of controlled substances strongly militate in favor of revocation . . ." *Id.* at 19. The Government notes that the Respondent: dispensed overlapping prescriptions at least 22 times; issued prescriptions to family members at least 27 times without adequate medical documentation in their medical records; issued 35 prescriptions for controlled substances to non-family members without any medical documentation; dispensed controlled substances at least 9 times to non-family members without any medical documentation, and an additional 71 times without adequate documentation. *Id.* at 20-21. The Government contends that these prescriptions and the dispensing of controlled substances were not for legitimate medical purposes, and were outside the usual course of professional treatment. *Id.* at 19.

The Government also points to the numerous recordkeeping violations that the Respondent committed. Those violations resulted in the Respondent being unable to account for thousands of dosages of controlled substances. *Id.* at 21. The Government notes that "careless recordkeeping is sufficient grounds unto

itself for the Administrator to revoke Respondent's COR." *Id.*

With respect to Factor Five, the Government argues that the Respondent's lack of candor supports revocation. *Id.* at 22. Specifically, the Government argues that the Respondent's initial denial of having any family medical files, and then his later producing them, suggests that the Respondent created the files "to thwart DEA's investigation." *Id.* The Government also argues that the Respondent was less than candid during his testimony on cross-examination, when he "was forced to admit that he had previously testified differently." *Id.* at 23.

The Government also contends that the Respondent has not accepted responsibility for his conduct, and therefore any remediation he has taken is irrelevant. *Id.* at 23-26. In addition, the Government seeks an adverse inference that the Respondent did not accept responsibility for his actions based upon the Respondent's refusal to answer questions of whether his actions fell below the standard of care or were outside the course of professional practice. *Id.* at 26-27. Finally, the Government also argues that even if the Respondent had accepted responsibility his actions were so egregious that revocation of his COR would be appropriate in this case. *Id.* at 27-28.¹⁸

II. The Respondent's Position

In the Respondent's Proposed Findings of Fact and Conclusions of Law¹⁹ ("Resp't Brief"), the Respondent argues that the public interest factors, when viewed in their totality, weigh in favor of his continued registration. ALJ-38, at 17. Initially, the Respondent argues that the Government's failure to present any evidence of action by the State of Connecticut against his medical license or evidence of any conviction of the Respondent weigh in favor of his continued registration. *Id.* at 17-18. Further, while the Respondent acknowledges past dispensing issues, he notes that he no longer dispenses controlled substances and he voluntarily surrendered all of his

controlled substances. *Id.* at 18. He argues that such action "supports a finding that his continued registration is consistent with the public interest at this time." *Id.* at 18.

The Respondent also contends that the Government failed to meet its burden of proof with respect to: paragraph 7(b) of the OSC concerning his issuance of overlapping prescriptions to a family member in a manner that constituted therapeutic duplication; paragraph 7(c) of the OCS, concerning writing a prescription for oxycodone to himself;²⁰ and paragraph 10 of the OSC concerning whether he maintained adequate security of his controlled substances. ALJ-38, at 19-22. With respect to Factor Five, the Respondent contends that he did not engage in other misconduct that may threaten the public health and safety. *Id.* at 22-25. Specifically, he contends that the statements he made to [M.J.] and [P.L.] comparing the relative dangers of schedule II controlled substances when compared to schedule IV controlled substances does not "rise to the level of creating even a possible threat to public health and safety." *Id.* at 23. The Respondent also denies the allegations contained in paragraph 11(b) of the OSC, because the testimony does not support a conclusion that the Respondent told the investigators that he did not write prescriptions to family members.²¹

The Respondent asserts that through his testimony, and by entering into 57 stipulations of fact, he has accepted responsibility for his actions. ALJ-38, at 25-27. The Respondent also asserts that his refusal to answer questions about whether his actions fell below the level of care or were outside the usual course of professional practice does not negate his acceptance of responsibility. *Id.* at 26. He argues that the few questions he declined to answer called for legal conclusions, but that he unequivocally accepted responsibility for his actions. *Id.* Finally, the Respondent notes that he has taken the following remedial measures: the Respondent has taken numerous continuing medical education

²⁰ Paragraph 7(c) of the OSC does not mention any specific controlled substance; rather it alleges that the Respondent issued prescriptions for controlled substances to himself and family members without any documentation of those prescriptions being placed in his medical record or the records of family members. Of note, at the hearing, the Respondent testified that the facts alleged in paragraph 7(c) of the OSC are true. Tr. 267-68.

²¹ The Resp't Brief does not address the allegation, also contained in paragraph 11(b), that the Respondent told the investigators that he did not have any patient files for his family members, but then later provided those records. ALJ-1, at 11.

¹⁷ The Post-Hearing Brief on Behalf of the Government has been marked as ALJ-37.

¹⁸ The Government did not address two significant issues in its Post Hearing Brief. First, the Government provided no analysis to support its allegation that the Respondent had failed to maintain adequate security of his controlled substances. Second, the Government's brief is silent concerning its allegation, under Factor Five, that the Respondent's *statement* to DEA investigators that he did not understand why they were concerned about "benzos" constitutes conduct which may threaten the public health and safety.

¹⁹ The Respondent's Proposed Findings of Fact and Conclusions of Law have been marked as ALJ-38.

courses; the Respondent has incorporated what he learned in the courses into his current daily medical practice; the Respondent has discontinued dispensing controlled substances; and the Respondent no longer prescribes or dispenses controlled substances to himself or family members. *Id.* at 27–30. Accordingly, the Respondent argues that, due to his acceptance of responsibility and the remedial actions he has taken, revocation of his COR is not appropriate at this time. *Id.* at 31.

Factors One & Three: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority, and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

In this case, it is undisputed that the Respondent holds a valid and current state license to practice medicine in Connecticut. The record contains no evidence of a recommendation regarding the Respondent's medical privileges by a relevant state licensing board or professional disciplinary authority. However, possession of a state license does not entitle a holder of that license to a DEA registration. *Mark De La Lama, P.A.*, 76 FR 20011, 20018 (2011). Rather, a state medical board's decision to allow a doctor to practice medicine is not dispositive as to whether the doctor's DEA registration is consistent with the public interest. *Patrick W. Stodola, M.D.*, 74 FR 20727, 20730 n.16 (2009).

The Respondent argues that the lack of state board action weighs against revocation. ALJ-38, at 17-18. Agency precedent, however, establishes that where the record contains no evidence of a recommendation by a state licensing board that absence does not weigh for or against revocation. *See Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011) (“The fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent's DEA certification is consistent with the public interest.”) Accordingly, Factor One does not weigh for or against revocation in this matter.

As to Factor Three, there is no evidence that Respondent has been convicted of an offense under either federal or Connecticut law “relating to the manufacture, distribution, or dispensing of controlled substances.” 21 U.S.C. 823(f)(3). However, there are a number of reasons why even a person

who has engaged in criminal misconduct may never have been convicted of an offense or even prosecuted for one. *Dewey C. MacKay, M.D.*, 75 Fed. Reg 49956, 49973 (2010), *pet. for rev. denied, MacKay v. DEA*, 664 F.3d 808, 822 (10th Cir. 2011). The Agency has, therefore, held that “the absence of such a conviction is of considerably less consequence in the public interest inquiry” and is therefore not dispositive. *Id.* Accordingly, Factor Three neither weighs for or against revocation in this case.

Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

Factors Two and Four are often analyzed together. *See, e.g., Fred Samimi, M.D.*, 79 FR 18698, 18709 (2014); *John V. Scalera, M.D.*, 78 FR 12092, 12098 (2013). Under Factor Two, the DEA analyzes a registrant's “experience in dispensing . . . controlled substances.” 21 U.S.C. 823(f)(2). Factor Two analysis focuses on an applicant's acts that are inconsistent with the public interest, rather than on an applicant's neutral or positive acts and experience. *Randall L. Wolff, M.D.*, 77 FR 5106, 5121 n.25 (2012) (explaining that “every registrant can undoubtedly point to an extensive body of legitimate prescribing over the course of [the registrant's] professional career”) (quoting *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009)). Similarly, under Factor Four, the DEA analyzes an applicant's compliance with federal and state controlled substance laws. 21 U.S.C. 823(f)(4). Factor Four analysis focuses on violations of state and federal laws and regulations. *Volkman v. DEA*, 567 F.3d 215, 223-24 (6th Cir. 2009) (citing *Gonzales v. Oregon*, 546 U.S. 243, 272, 274 (2006)); *see Joseph Gaudio, M.D.*, 74 FR 10083, 10090-91 (2009).

Here, the Government alleges that revocation of the Respondent's COR is appropriate under Factors Two and Four for four reasons: (1) improper recordkeeping; (2) improper prescribing to himself and family members; (3) improper prescribing to patients; and (4) failure to maintain adequate security. ALJ-1, 13, 30, 37.

I. Improper Recordkeeping

Registrants are required to keep certain records and inventories of their controlled substances. *Paul H. Volkman, M.D.*, 73 FR 30630, 30644 (2008). Among those requirements, registrants are to: (1) maintain adequate dispensing

records and logs, see 21 CFR 1304.21(a) and 1304.22(c); (2) maintain receipt records for all controlled substances received, see 21 CFR 1304.04(a) and 1304.21(a); (3) maintain records of controlled substances listed in Schedules III–V, separate from other records, see 21 CFR 1304.04(f)(2); and (4) perform and maintain a biennial inventory, see 21 CFR 1304.11(c). Such recordkeeping is one of the central features of the Controlled Substances Act (“CSA”) because “a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.” *Superior Pharmacy I & Superior Pharmacy II*, 81 FR 31310, 31337 (2016) (quoting *Volkman*, 73 FR at 30644). The Supreme Court has noted that “[t]he CSA and its implementing regulations set forth strict requirements regarding . . . recordkeeping.” *Gonzales v. Raich*, 545 U.S. 1, 14 (2005). However, the DEA has also held that, where non-egregious recordkeeping errors are acknowledged and remedied promptly, revocation may not always be required. *See Terese, Inc., D/B/A Peach Orchard Drugs*, 76 FR 46843, 46848 (2011).

First, the Government alleged that the Respondent failed to maintain accurate dispensing records and logs, in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.21(a) and 1304.22(c), and Conn. Agencies Regs. § 21a–326–1(d)(2), (6). ALJ-1, at 2–3. The Respondent, however, stipulated to numerous facts that establish by a preponderance of the evidence that he repeatedly failed to maintain accurate dispensing records and logs. Stip. of Fact 4-11. Accordingly, the Government's allegations that the Respondent failed to maintain accurate dispensing records and logs, as alleged in paragraphs 4(b), 4(d), and 4(f) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Second, the Government alleged that the Respondent failed to maintain controlled substance receipts for orders of controlled substances, in violation of 21 U.S.C. 842(a)(5), 21 CFR 1304.04(a) and 1304.21(a), Conn. Gen. Stat. § 21a-254(c), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 3-4. Here, too, the Respondent stipulated to numerous facts that established by a preponderance of the evidence that he repeatedly failed to maintain controlled substance receipts for orders of controlled substances that he received in his office. Stip. of Fact 12–18. Accordingly, the Government's allegations that the Respondent failed to maintain controlled substance receipts

for orders of controlled substances, as alleged in paragraphs 4(i)–4(o) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Third, the Government alleged that the Respondent failed to maintain records of controlled substances listed in Schedules III–V, separate from other records, in violation of 21 CFR 1304.04(f)(2), Conn. Gen. Stat. § 21a-254(f), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4. With respect to this allegation, the Respondent stipulated that he had failed to keep his records of his Schedules III–V controlled substances separate from his records of other controlled substances. Stip. of Fact 19. This factual stipulation establishes by a preponderance of the evidence that the Respondent failed to maintain records of controlled substances, listed in Schedules III–V, separate from other records. Accordingly, that allegation, as set forth in paragraph 4(p) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration.

Fourth, the Government alleged that the Respondent failed to perform and maintain a biennial inventory of his controlled substances, in violation of 21 U.S.C. 827(a)(1), 21 CFR 1304.11(c), Conn. Gen. Stat. § 21a-254(h), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 4. The Respondent stipulated to the fact that he failed to perform and maintain a biennial inventory of his controlled substances. Stip. of Fact 20. This stipulation satisfies the preponderance of evidence standard to prove that the Respondent did not perform or maintain a biennial inventory as he was required to do. Accordingly, the Government's allegation that the Respondent failed to perform and maintain a biennial of his controlled substances, as alleged in paragraph 4(q) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration.

Fifth, the Government alleged that as a result of the Respondent's poor record keeping he was unable to account for significant quantities of several different controlled substances he received from his supplier, in violation of 21 U.S.C. 827(a)(3), 21 CFR 1304.21(a), and Conn. Agencies Regs. § 21a-326-1(d)(2), (6). ALJ-1, at 2-3. The Respondent conceded that these allegations were true. Stip. of Fact 4, 6, 8, 10, 11. These stipulations satisfy the preponderance of evidence standard to prove that the Respondent was unable to account for significant quantities of his controlled substances. Accordingly, the Government's

allegations that the Respondent was unable to account for quantities of controlled substances he received from his supplier, as alleged in paragraphs 4(a), 4(c), 4(e), 4(g), and 4(h) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

Finally, the last recordkeeping violation the Government alleged was that the Respondent failed to report to the Connecticut State Commissioner of Consumer Protection that he was dispensing drugs, and that the Respondent failed to biennially notify the Commissioner of his intent to continue to dispense drugs, in violation of Conn. Gen. Stat. §§ 20-14f and 21a-317, and 21 CFR 1306.03(a)(1). ALJ-1, at 5. The Respondent stipulated to these facts. Stip. of Fact 21. This stipulation meets the evidentiary standard of preponderance of the evidence. Accordingly, the Government's allegation that the Respondent failed to report to the Commissioner that he was dispensing drugs and intended to continue to do so, as alleged in paragraphs 4(r) of the OSC, is **SUSTAINED** and weighs in favor of revocation of the Respondent's DEA registration.

II. Improper Prescribing to Himself & Family Members

Under federal regulations, “[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). The prescription requirement prevents “doctors from peddling to patients who crave the drugs for . . . prohibited uses.” *George C. Aycock, M.D.*, 74 FR 17529, 17541 (2009) (citing *Gonzales v. Oregon*, 546 U.S. 243, 274 (2006)). Accordingly, “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription[,] . . . and the person knowingly . . . issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” 21 CFR 1306.04(a).

Under the CSA, it is fundamental that a practitioner must establish and maintain a legitimate doctor-patient relationship in order to act in the usual course of professional practice and to issue a prescription for a legitimate medical purpose. *Fiaz Afzal, M.D.*, 79 FR 61651, 61653 (2014); see also *Samuel Mintlow, M.D.*, 80 FR 3630, 3648 (2015) (citing *United States v. Moore*, 423 U.S. 122, 142–43 (1975)). The CSA “generally looks to State law

and standards of medical practice to determine whether a doctor and patient have established (and are maintaining) a bona fide doctor-patient relationship.” *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010).

Here, the Government alleged that the Respondent repeatedly issued controlled substance prescriptions to himself and his family members for other than legitimate medical purposes and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 CFR 1306.04(a). ALJ-1, at 5-6. Specifically, the Government alleged in the OSC: [7(a)] that the Respondent either issued or dispensed overlapping prescriptions of controlled substances to himself and a family member, N.A., constituting early refills; [7(b)] that the Respondent issued to N.A. overlapping prescriptions for controlled substances that are similar or have similar effects on the body, constituting therapeutic duplication; [7(c)] that the Respondent issued to himself, and his family members N.A. and U.A., prescriptions for controlled substances without any documentation of those prescriptions or the bases for them in the medical records; [7(d)] that the Respondent either issued a prescription or dispensed controlled substances to himself without adequate documentation in the medical record; [7(e)] that the Respondent issued prescriptions to N.A. for a variety of controlled substances without adequate documentation in the medical record; and [7(f)] that the Respondent issued a controlled substance prescription to a family member G.A. and inadequately documented that prescription or the basis for it in G.A.'s medical record. ALJ-1, at 5–6.

Regarding the allegations in paragraph 7(a) of the OSC, the Respondent stipulated to the factual allegations that he issued overlapping prescriptions of controlled substances to himself and a family member, N.A., constituting early refills. Stip. of Fact 24. Similarly, regarding the allegations in paragraphs 7(d), 7(e), and 7(f), the Respondent stipulated to the factual allegations that he issued a prescription or dispensed controlled substances to himself, or to family members, N.A. and G.A., without adequate documentation in the medical record. Stip. of Fact 25-27.

There are, however, two allegations that the Respondent disputes. Specifically, the Respondent contests the allegations contained in paragraph 7(b) of the OSC. That paragraph alleges that the Respondent issued overlapping prescriptions for controlled substances

to a family member, N.A. It further alleges that those prescriptions have similar effects on the body, constituting therapeutic duplication. The Respondent also contests paragraph 7(c) of the OSC. ALJ-38, at 21. That paragraph alleges that the Respondent issued prescriptions for controlled substances to himself and family members N.A. and U.A. without any documentation or bases for the prescriptions in the patients' medical records. ALJ-1, at 5.

With regards to the allegation in paragraph 7(b) of the OSC, the Respondent argues that "the Government has failed to meet its burden of proof that the prescription constituted therapeutic duplication." ALJ-38, at 21. The Respondent points to a notation in the Respondent's patient file for N.A., dated March 5, 2014, which indicates "Lunesta doesn't help changed to Ambien 10 mg #30." GE-11, at 7; ALJ-38, at 21. Additionally, the Respondent argues that Dr. Perrin testified that he did not know whether patient N.A. was taking the medication in an overlapping fashion. Tr. 189; ALJ-38, at 21. Furthermore, the Respondent argues that he knew patient N.A. would not take the two medications at the same time because patient N.A. is his son, who lived with the Respondent. ALJ-38, at 21; Finding of Fact ("FF") 41. N.A. came to the Respondent and told him that the medication he was currently taking was not working and asked the Respondent if he could prescribe something else. FF 41.

With regards to the allegation contained in paragraph 7(c) of the OSC, the Respondent argues that "[t]he Government has failed to prove by a preponderance of the evidence that Respondent prescribed oxycodone to himself as alleged in Paragraph 7c" of the OSC. ALJ-38, at 21. However, as previously discussed, 7(c) alleges that the Respondent issued prescriptions for controlled substances to himself and his family members, N.A. and U.A., without any documentation or bases of those prescriptions in the patients' medical records. ALJ-1, at 5. It does not mention oxycodone at all. Furthermore, the Respondent admitted at the hearing to the factual allegations contained in 7(c). Tr. 267-68; FF 42.²²

In order to establish the standard of care for the State of Connecticut, the Government presented the expert opinion of Dr. Perrin. Dr. Perrin testified

²² When inquiring about paragraph 7(c), Government counsel states, "My question on this was whether you admit that this occurred. It's a factual question." Tr. 268. To which the Respondent replied, "Yeah, it's a factual question. This occurred, yes, it occurred." Tr. 268.

that the Respondent's practice of issuing overlapping prescriptions of controlled substances to himself and to his family members fell below the standard of care in the State of Connecticut. FF 56; Stip. of Fact 24. The concern with issuing overlapping prescriptions is that if the medications are taken simultaneously there is a potential for harm to the patient. FF 56. Furthermore, there is "a cumulative effect of too much potentially sedating medication that also has addictive potential." Tr. 165; FF 56.

Additionally, according to Dr. Perrin, the Respondent's practice of issuing a prescription or dispensing controlled substances to himself or his family members, without adequate documentation in the medical record, is below the standard of care in the State of Connecticut. FF 60; Stip. of Fact 25-27. Dr. Perrin reasoned that with any prescription of a controlled substance, it is "important to provide adequate documentation as to the precise reason for why [the] particular substance is indicated." Tr. 166; FF 60. Moreover, there needs to be "an appropriate diagnosis that underlies the prescribing of said substance, and [there] has to be documentation that's beyond cursory to substantiate the choice of prescribing said substance." Tr. 166; FF 61. Where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance, there is no legitimate medical purpose for that prescription. FF 61.

Significantly, Dr. Perrin also opined that where a doctor's prescriptions are outside the standard of care, the doctor is also prescribing outside the usual course of professional practice. Tr. 183. Accordingly, Dr. Perrin's credible and persuasive testimony, coupled with the Respondent's admissions, are sufficient to establish that the Respondent's actions of issuing overlapping prescriptions for controlled substances and issuing prescriptions for controlled substances without adequate documentation in the patients' medical records fell below the standard of care in the State of Connecticut and that these prescriptions were not issued for a legitimate medical purpose in the usual course of professional practice.

Dr. Perrin identified two sets of overlapping prescriptions issued by the Respondent to his son, N.A. First, Dr. Perrin identified Government Exhibit 13 as a prescription for Lunesta (with five refills) issued by the Respondent to his son, N.A., on December 6, 2012. Tr. 156-57. Lunesta is a sedative hypnotic agent that is used to treat insomnia. Tr. 156-57. Dr. Perrin identified Government

Exhibit 14 as a prescription for Ambien (with five refills) issued by the Respondent to N.A. on March 23, 2013. Tr. 156-57. Like Lunesta, Ambien is a sedative hypnotic used to treat insomnia. Tr. 156. In Dr. Perrin's opinion, the refills indicated on Government Exhibit 13 overlap with the date on the prescription on Government Exhibit 14, and the combination of these two prescriptions constitutes therapeutic duplication. Tr. 157. Second, Dr. Perrin identified Government Exhibit 18 as a prescription for Lunesta (with five refills) issued by the Respondent to N.A. on February 24, 2014. FF 51. Dr. Perrin also identified Government Exhibit 19 as a prescription for Ambien (with 5 refills) issued by the Respondent to N.A. on March 5, 2014. FF 52. In Dr. Perrin's opinion, Government Exhibits 18 and 19 are overlapping prescriptions.²³ FF 53.

In Dr. Perrin's opinion, the notation in the Respondent's patient file for why he changed N.A.'s prescription to Ambien is not sufficient to justify the therapeutic duplication. FF 55. However, it was also Dr. Perrin's opinion that prescribing overlapping prescriptions could be legitimate if there was an explanation as to why one substance was being withdrawn in favor of another; for example, due to an adverse reaction, intolerance, or truly ineffective after a fair trial. Tr. 170-71. As the Respondent argues, he knew that his son was not taking both medications at the same time, noting that his son lived with him. He also testified that he noted in his son's patient file that Lunesta was not working based on what his son had told him, so he changed his son's prescription to Ambien. GE-11, at 7; ALJ-38, at 21. I find that the note in N.A.'s patient file clearly indicates why the Respondent changed his son's prescription from Lunesta to Ambien. Further, based on the evidence before me, it is apparent that the Respondent was intimately involved in his son's welfare. See *Belinda R. Mori, N.P.*, 78 FR 36582, 36587 (2013).

Accordingly, the Government's allegations that the Respondent repeatedly issued controlled substance prescriptions to himself and his family

²³ Paragraph 7(b) of the OSC alleges that the Respondent issued overlapping prescriptions to his son in 2014. The Government's evidence would support a finding that the Respondent issued only one overlapping prescription to his son in 2014, the one issued on March 5, 2014. See GE-19. The Respondent was never placed on notice that the Government would be introducing prescriptions from 2012 and 2013, GE-13-14, to support this allegation. See ALJ-37, at 6, para. 25. Accordingly, when making my Recommended Decision in this case, I place no weight on the evidence of an overlapping prescription that occurred in 2013.

members for other than legitimate medical purposes and outside the course of professional practice, as alleged in paragraphs 7(a) and 7(c)-7(f) of the OSC, are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration. However, as discussed above, I find that the Government has not established, by a preponderance of the evidence, the allegation contained in paragraph 7(b) of the OSC. Therefore, the allegation contained in paragraph 7(b) of the OSC is **NOT SUSTAINED**.²⁴

III. Improper Prescribing to Patients

The Government alleged that the Respondent repeatedly issued controlled substance prescriptions to patients for other than a legitimate medical purpose and outside the course of professional practice, in violation of Conn. Gen. Stat. §§ 20-14e(b), 21a-322(3), (8), (10), 21a-252(a), Conn. Agencies Regs. § 21a-326-1(c), (d), and 21 CFR 1306.04(a). ALJ-1, at 6-10. Specifically, the Government alleged that the Respondent issued multiple overlapping prescriptions for controlled substances to his patients, issued prescriptions to his patients without any, or sufficient, documentation or bases for the prescriptions in the patients' records, and dispensed controlled substances to patients from his office supply without any, or sufficient, documentation of dispensing those controlled substances, or the bases for them in the patients' medical records. ALJ-1, at 6-10.

The Respondent stipulated to all of the factual allegations regarding improper prescribing to patients. Stip. of Fact 28-57. Specifically, the Respondent admitted that on at least 20 occasions between 2012 and 2014, he issued multiple overlapping prescriptions for controlled substances to at least four separate patients. Stip. of Fact 29-32. The Respondent admitted that on at least 35 occasions between 2010 and 2014, he issued prescriptions to at least eight separate patients without any documentation or bases for the prescriptions in their medical records. Stip. of Fact 33-40. The Respondent admitted that on at least nine occasions between 2012 and 2014, he dispensed controlled substances to at least three of his patients from his office supply without any documentation or bases for dispensing those controlled substances in their medical records.

Stip. of Fact 41-43. The Respondent admitted that on at least 26 occasions between 2011 and 2014, he issued prescriptions to at least seven patients without sufficient documentation or bases for the prescriptions in their medical records. Stip. of Fact 44-50. Finally, the Respondent admitted that on at least 45 occasions between 2010 and 2014, he dispensed controlled substances to at least seven patients from his office supply without sufficient documentation or bases for them in their medical records. Stip. of Fact 51-57.

The Government again offered the testimony of Dr. Perrin to establish the standard of care in the State of Connecticut regarding the allegations of the Respondent's improper prescribing to patients. Dr. Perrin testified that the Respondent's practice of issuing multiple overlapping prescriptions for controlled substances fell below the standard of care in the State of Connecticut. FF 56. Dr. Perrin further explained that the concern with issuing overlapping prescriptions is the potential for diversion with additional controlled substances floating around. Tr. 207; FF 57. Additionally, Dr. Perrin noted that where a patient's medical record does not contain adequate documentation to explain the reason for prescribing a highly addictive controlled substance, there is no legitimate medical purpose for the prescription. Tr. 202; FF 61. Therefore, the Respondent's practice of issuing controlled substance prescriptions or dispensing controlled substances from his office supply to patients without adequate documentation or bases for the prescription or dispensing in the patient's medical record fell below the standard of care in the State of Connecticut, and was also outside the usual course of professional practice. Tr. 183; FF 61.

Dr. Perrin's testimony, coupled with the Respondent's admissions, is sufficient to establish that the Respondent issued controlled substances for other than a legitimate medical purpose and outside the course of professional practice. Accordingly, the Government's allegations contained in paragraph 9 of the OSC are **SUSTAINED** and weigh in favor of revocation of the Respondent's DEA registration.

IV. Failure to Maintain Security of Controlled Substance.

The Government alleged that the Respondent failed to maintain adequate security of his controlled substances. Specifically, the Government alleged that the Respondent's "controlled

substances were stored in an unlocked cabinet in an unlocked room . . . in the front-desk reception area . . .," in violation of 21 CFR 1301.75(b) and Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-326-1(d). ALJ-1, at 11. Clearly, a registrant must maintain the physical security of his controlled substances to prevent unlawful diversion. *Jerry Neil Rand, M.D.*, 61 FR 28895, 28897 (1996). Further, registrants are required to store controlled substances in "a securely locked, substantially constructed cabinet." 21 CFR 1301.75(b). When a registrant leaves controlled substances unattended, the controlled substances must be placed in a proper storage cabinet. *Jeffery J. Becker, D.D.S.*, 77 FR 72387, 72405 (2012) (citing to *D-Tek Enter.*, 56 FR 28926 (1991), and the Merriam-Webster Dictionary).

The Government bears the burden of proof concerning this allegation. 5 U.S.C. 556(d); 21 CFR 1301.44(e); *Jack A. Danton, M.D.*, 76 FR 60900, 60920 (2011). To prove this allegation, the Government presented the testimonies of [R.M.], [N.C.], [P.L.], and [M.J.]. In addition, the Respondent also testified on this issue. Initially, no witness testified that the Respondent stored his controlled substances in the "front-desk reception area" of his office. Second, it is also clear that prior to February 21, 2014, the Respondent stored his controlled substances in a louvered closet that did not have a lock on it. FF 33, 34, 35, 36, 38. Third, the closet where the Respondent's controlled substances were stored was located in a room ("examination room"), which contained a patient examination table and expensive unused medical equipment. FF 32, 33, 34, 35.

The question of whether the examination room where the controlled substances were stored, in an unlocked closet, was locked, is not readily clear. Neither [R.M.] nor [N.C.] could recall if the examination room was locked on March 4, 2016. Tr. 21-22, 42. [P.L.] testified that the door to the examination room was not locked when she was at the Respondent's office in January 2014, but she did not know if the door was locked when she was there in February 2014. Tr. 58, 61. [M.J.]'s testimony concerning whether the door to the examination room was locked during her visits to the Respondent's office in January 2014 and again in February 2014, is not particularly precise. Concerning the January visit she testified that the Respondent "told us that [the controlled substances] were stored in an unlocked examination room in an unlocked closet, which we also later visually observed." Tr. 85. It is not clear just what was "observed." When

²⁴ There was lengthy discussion during the hearing concerning the issue of whether it is below the standard of care in the State of Connecticut for a physician to self-prescribe. That issue is not squarely before me, however, because the OSC does not contain that allegation.

asked if the examination room was locked in February 2014, [M.J.] testified, "Not to my recollection." Tr. 95. She noted, however, that she was not the first one in the room; rather, she was right behind another investigator who "opened it right up." *Id.* Further confusing the matter, she could not recall, however, if the Respondent had led them into the examination room. *Id.* Thus, the Government presented four witnesses who had a total of eight opportunities²⁵ to observe whether the door to the examination room was locked prior to their entrance into the room. Only [P.L.] testified that the room was unlocked on her first visit to the Respondent's office on January 31, 2014, but she provided no explanation of how or why she recalled that fact.

The Respondent testified that he kept the examination room locked because he had kept expensive medical equipment in the room since about 2009. Tr. 229-30, 301-03. The Respondent also testified: that the outside door to his clinic was kept locked except during normal business hours, Tr. 228-29; that his office had a "key pad" security alarm and an alarm would sound if someone entered the clinic without disabling the alarm system, Tr. 228; and that he had security cameras installed in his clinic. Tr. 228.

Comparing the testimony of the Government's witness with that of the Respondent, and considering the Respondent's stated reason for keeping the door to the examination room locked, I find that the preponderance of the evidence does not support the conclusion that Respondent stored his controlled substances in an unlocked room. Rather, the evidence supports the conclusion that the door to the examination room was kept locked.

Here the Government charged that the Respondent's security measures violated 21 CFR 1301.75(b), which requires that Schedule II-V controlled substances "be stored in a securely locked, substantially constructed cabinet." While the regulations do not define the term "cabinet," the New College Edition of the *American Heritage Dictionary of the English Language* (1976) includes the following definition of "cabinet": "a small or private room set aside for some specific activity." Further the *Danton* decision suggests that that the term "cabinet" has a broader meaning than the Government seeks to impose.

In *Danton*, DEA investigators found oxycodone in a closet in Danton's office. 76 FR at 60907-08, 60920. The closet was in the dispensing area of the clinic. *Id.* at 60920. The closet also contained security monitoring equipment. *Id.* The investigators, however, did not know if the closet was locked or even if it could be locked. *Id.* The DEA alleged that Danton had violated 21 CFR 1301.75 because the oxycodone was in a closet that "was not a securely locked, substantially constructed cabinet suitable for the storage of control substances." *Id.* Because the Government failed to demonstrate how the closet failed to meet the requirements of the regulation, the Administrator found that the Government failed to prove that Danton had violated 21 CFR 1301.75(b). *Id.*

In this case the Government's focus in charging the Respondent with failing to maintain adequate security of his controlled substances was whether those substances were in a locked cabinet. *See* ALJ-1, at 11; Tr. 22-23, 39, 43, 67, 95, 134. That is understandable due to the language in 21 CFR 1301.75(b) that controlled substances are to "be stored in a securely locked, substantially constructed cabinet." There are no further regulations, however, that define those terms. *See* Tr. 67-68. Further when questioned on DEA guidance related to a substantial cabinet, [M.J.] testified, "It needs to be substantially secure. The intent of the storage is to have it be secure so as to prevent from theft or diversion." Tr. 123. Further, 21 CFR 1301.71(b) states that the Administrator can consider *any* of 15 different security related factors in deciding whether a registrant was in "substantial compliance" with 21 CFR 1301.75(b). Thus the answer to the question of whether the Respondent failed to maintain adequate security of his controlled substances is not solely dependent on the answer to the question of whether the container in which the controlled substances were located was itself locked. If that were the case, the 15 factors and the language of "substantial compliance" contained in 21 CFR 1301.71(b) would be meaningless.

In this case the Respondent kept his controlled substances in a locked room where he stored high value medical equipment. Second, the Respondent's office was protected by a security system and by cameras. Third, there were only a total of three individuals who worked in the Respondent's office. Fourth, there is no evidence that the Respondent's office was located in a high crime area or that there was an absence of local police protection.

Finally, there is no evidence that the examination room was being used for any purpose other than to store high valued medical equipment and the Respondent's controlled substances.

Given the nature of the evidence contained in the administrative record, it is not necessary to find that the "examination room" met the requirements of 21 CFR 1301.75(b). Rather, in light of the absence of evidence as to why the "examination room" failed to satisfy the requirements of 21 CFR 1301.75(b), and considering the five points detailed in the paragraph above, as well as the guidance contained in *Danton*,²⁶ I find that the Government failed to prove that the Respondent violated 21 CFR 1301.75(b) when he stored his medication in the locked "examination room." Further, considering [M.J.]'s testimony that the "intent of the storage is to have it be secure so as to prevent from theft or diversion," Tr. 123, the record established that the Respondent clearly met that intent.

In light of the discussion above, and giving due consideration to the factors contained in 21 CFR 1301.71(b), the Government's allegation that the Respondent violated 21 CFR 1301.75(b) is **NOT SUSTAINED**. Furthermore, the Government's allegations that the Respondent violated the cited provisions of Connecticut Regulations, Conn. Agencies Regs. §§ 21a-262-6(a)-(c), 21a-32601(d), with respect to his storage of his controlled substances are not sustained.²⁷

Factor Five: Other Conduct Which May Threaten the Public Health and Safety

Under Factor Five, the DEA is authorized to consider "other conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5). This factor encompasses "conduct which creates a probable or possible threat (and not only an actual [threat]) to public health and safety." *Jacobo Dreszer, M.D.*, 76 FR 19386, 19386 n.3 (2011). Under Factor Five, the Government has alleged two bases upon which it seeks to revoke the Respondent's COR. First, citing *Dreszer*, the Government alleges that a statement that the Respondent made to DEA and Connecticut investigators that "'benzos' [were] not worthy of DEA investigation, particularly given how other doctors in [his] community were distributing Schedule II controlled substances," is conduct that may threaten the public

²⁵ [M.J.] and [P.L.] each had three opportunities to observe the door. They went to the Respondent's office twice on January 31, 2014, and once on February 21, 2014. FF 38-39. [R.M.] and [N.C.] were both at the Respondent's office on March 4, 2016. FF 15, 21.

²⁶ I also considered the Administrator's analysis in *Howard N. Robinson, M.D.*, 79 FR 19356, 19372 (2014).

²⁷ The Government made no argument in its post-hearing brief concerning paragraph 10 of the OSC.

health and safety. ALJ-1, at 11, para. 11(a). Next the Government alleges that the Respondent attempted to mislead DEA and Connecticut investigators by denying that he had issued prescriptions to family members and by denying that he had any medical records concerning his treatment of family members. *Id.* at para. 11(b). The Government further alleged that several days after the Respondent denied having such records, he produced a file concerning his treatment of family members and that the delay in producing the records “strongly suggest[s] that the file was created after the fact in response to the DEA’s investigation.” *Id.* The Government alleges that such conduct is evidence of a lack of candor, which is “an important factor when assessing whether a physician’s registration is consistent with the public interest.” *Id.* at 11-12 (citing *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005)). In its Post-Hearing Brief the Government argues that the Respondent was also less than candid during his testimony on cross-examination, when he “was forced to admit that he had previously testified differently.” ALJ-37, at 22-23.

I. The “Benzos” Statement

Paragraph 11(a) of the OSC alleges that the Respondent’s purported statement that “benzos” [were] not worthy of DEA investigation, particularly given how other doctors in [his] community were distributing Schedule II controlled substances,” ALJ-1, at 11, is conduct that should be considered under Factor Five. The only authority the Government cites for its position is the *Dreszer* decision. In its Post-Hearing Brief, the Government does not even address this issue. ALJ-37.

Based upon my review of the testimony, I concluded that the Respondent made a statement to [M.J.] and [P.L.] that closely matches the language cited in the paragraph 11(a) of the OSC. But my review of the *Dreszer* decision does not convince me that such a statement would be a basis for revocation under Factor Five. As the Respondent appropriately argues, “nothing in *Dreszer* stands for the proposition that Respondent’s simple statements . . . rise to the level of creating even a possible threat to public health or safety.” ALJ-38, at 23. While I need not decide if language by itself, wherein the individual simply states an opinion, would ever give rise to actionable **conduct**, the Government has come nowhere near meeting its burden of proof concerning the language quoted above. Accordingly, the

allegations contained in paragraph 11(a) of the OSC are **NOT SUSTAINED**.

II. Attempt to Mislead

In paragraph 11(b) of the OSC, the Government alleged that the Respondent engaged in acts wherein he attempted to mislead the DEA during its investigation concerning him. First, the Government alleges that the Respondent told the investigators that he did not issue prescriptions to members of his family. Second, the Government alleges that the Respondent told the investigators that he did not have any records concerning the medical treatment he provided to family members, and then “several days” later the Respondent produced a file of those records. The Government further alleges that the manner in which the Respondent produced the records “strongly suggests that the file was created after the fact . . .” ALJ-1 at 11.

A. Statements Concerning Prescribing to Family Members

The evidence of whether the Respondent told the investigators that he did not prescribe to family members is a bit convoluted. [P.L.] testified that the Respondent initially told the investigators that he did not prescribe to family members because he did not want to take responsibility of something going wrong. Tr. 55-56. [P.L.] then showed him some prescriptions he had written for family members and the Respondent verified he had written the prescriptions. Tr. 56. On cross-examination, however, [P.L.] testified that she did not recall the exact language the Respondent had used, and that it was possible that he had answered “mostly not,” when he was asked if he wrote prescriptions to family members. Tr. 70. [M.J.], who sat through [P.L.]’s testimony, testified that the Respondent initially denied writing prescriptions to family, but she, too, indicated that his answer was “mostly not.” Tr. 86-87. The Respondent testified that he acknowledged writing prescriptions to family members, but his position was “mostly no.” Tr. 255.

Keeping in mind that the Government has the burden of proof concerning each of its allegations, I find that the testimony does not support the conclusion that Respondent denied that he had written prescriptions to members of his family. Both of the Government witness on this issue, as well as the Respondent, used the terms “mostly not.” Further, even if the Respondent initially denied writing to family members, he quickly corrected the record. Under these facts, I find no

“attempt to mislead.”²⁸ Accordingly, the Government’s allegation, contained in Paragraph 11(b) of the OSC, that the Respondent told the investigators that he did not issue prescriptions to members of his family in an attempt to mislead them is **NOT SUSTAINED**.

B. Fabrication of Family Medical Records

With respect to the family medical records, which the Respondent produced, the Government alleged that after the Respondent denied having the records he produced them a few days later. The Government further suggests that the Respondent used the time to create the file “after the fact in response to the DEA’s investigation . . .” ALJ-1, at 11. The Government has not alleged, nor has it argued, that the Respondent lied to the investigators when he told them he did not have family medical records. Rather, the Government’s allegation in paragraph 11(b) of the OSC and in its argument in its Post Hearing Brief is that the Respondent falsified the medical records “to thwart DEA’s investigation.” ALJ-37, at 22. In support of this allegation the Government cited the same two cases in both the OSC and its post-hearing brief: *Jerry Neil Rand, M.D.*, 61 Fed. Reg. 28895 (1996), and *Nelson A. Smith, D.D.S.*, 58 Fed. Reg. 65403 (1993).

The testimony supporting the allegation that the Respondent told [M.J.] and [P.L.] that he did not have family medical records is not contradicted. [P.L.] testified that the Respondent was asked if the investigators could see the medical records concerning his treatment of family members and “[h]e did not have any.” Tr. 56. [M.J.] also testified that the Respondent denied having any patient charts for his family members. Tr. 87. The Respondent did not provide direct testimony on this issue, but he did testify that he did not intentionally mislead the investigators. Tr. 256.

The evidence is also clear that the Respondent did not produce the file containing the patient charts for himself and members of his family “several days” after he told the investigators that he did not have such files. [M.J.] and [P.L.] met with the Respondent on January 31, 2014. FF 15. It was on that date that the Respondent told [M.J.] and [P.L.] he did not have treatment files for family members. FF 16. [M.J.] and [P.L.] found out about the patient charts from

²⁸I also note that the Respondent has some difficulty hearing, which certainly could have contributed to miscommunication. Tr. 254; *see also* Tr. 210.

a doctor who worked with the Respondent. Tr. 88. The Respondent also mentioned the patient files before they were produced. Tr. 88. Then, about 18 months after the January 31, 2014 meeting with the Respondent, [M.J.] “submitted an administrative subpoena . . . in July of 2015 for the family records . . . and [the Respondent] returned them to [her] . . . within a week or so.” Tr. 88. Thus the OSC does not paint an accurate picture of what actually happened.²⁹

While the facts underlying the allegation contained in paragraph 11(b) of the OSC are relatively clear from the record, *the allegation is one of specific intent*—that the Respondent *attempted to mislead* by first denying that he had family medical files and then producing them a few days later after he had created them. As with any allegation, the Government bears the burden of proof regarding its claim that the Respondent *attempted to mislead* DEA investigators during their investigation. See ALJ-1, at 11. Concerning this allegation, however the Government’s case rests primarily upon conjecture. Further, “under the substantial evidence test, the evidence must ‘do more than create a suspicion of the existence of the fact to be established.’” *Alvin Darby, M.D.*, 75 Fed. Reg. 26993, 26999 n.31 (2010) (citing *NLRB v. Columbian Enameling & Stamping Co.*, 306 U.S. 292, 300 (1939)). In my view, suspicion is all the Government has presented on the issue of whether the Respondent created the family medical files after he was asked about them on January 31, 2014.

I, therefore, reject the Government’s allegation that the Respondent fabricated Government Exhibit 11 in an attempt to mislead the DEA during its investigation. First, unlike the two cases the Government relies upon, *Rand* and *Smith*, the Government presented no direct evidence that the Respondent either altered patient files or falsified those files. Second, the Respondent did not quickly produce the files after he first denied having them; rather he produced them 18 months later, and in response to a subpoena. Third, a review of Government Exhibit 11, and comparing it to prescriptions written to

family members, reveals nothing suggestive of fabrication, and the Government has not identified or presented evidence of any specific examples of fabrication. Finally, the Respondent is a well-educated medical doctor, who immigrated to the United States and passed the Foreign Medical Graduates exam only three months after he arrived here. He appears to be an intelligent and well-spoken individual. Certainly if the Respondent created Government Exhibit 11 to mislead the DEA he could have done a far better job in fabricating medical records for himself and for family members. In fact, it is the poor quality of those medical records that the Government relied upon as the bases of other allegations the DEA successfully brought against the Respondent in the OSC. See ALJ-1, at 5-6, para. 7(c)-(f). Accordingly, the Government’s allegation, in Paragraph 11(b) of the OSC, that the Respondent told the investigators that he did not have any records with respect to his family members and then several days later produced those records *in an attempt to mislead* the DEA is **NOT SUSTAINED**.

III. Lack of Candor

In its Post-Hearing Brief, the Government argues that the Respondent demonstrated a lack of candor during his testimony at the hearing on March 13, 2017. ALJ-37, at 22-23. In addition, the Government proposed 12 facts that it contends support its argument that the Respondent’s testimony demonstrated a lack of candor. ALJ-37, at 11-12.

The DEA has consistently held that “[c]andor during DEA investigations, regardless of the severity of the violations alleged, is considered by the DEA to be an important factor when assessing whether . . . registration is consistent with the public interest.” *Jeri Hassman, M.D.*, 75 Fed. Reg. 8194, 8236 (2010) (citing *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005)). For example, the DEA held that a respondent’s lack of candor weighed against his registration under Factor Five when he lied to DEA investigators “when first confronted” about his wrongful conduct. *John V. Scalera, M.D.*, 78 Fed. Reg. 12092, 12100 (2013). The DEA “places great weight on a registrant’s candor, both during an investigation and in [a] subsequent proceeding.” *Robert F. Hunt, D.O.*, 75 Fed. Reg. 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy*, 72 Fed. Reg. 74334, 74338 (2007)). Thus, the DEA may consider a respondent’s lack of candor to be a threat to public health

and safety. *Annicol Marrocco, M.D.*, 80 Fed. Reg. 28695, 28705 (2015).

The Government contends that the Respondent was less than candid when testifying about: the number of Suboxone patients the Respondent currently treats; whether he had ever provided a prescription in exchange for service; whether he had told investigators that benzodiazepines were not commonly diverted or abused; whether he would prescribe controlled substances to someone who said they were giving the controlled substances to someone else; and whether he had ever taken drugs home to give to a family member. ALJ-37, at 11-12. Many of these issues were raised in context of testimony the Respondent apparently gave in prior hearings or depositions. The Government, however, did not offer the transcripts of those prior testimonies. Furthermore, even the transcripts of prior testimony, which may differ from testimony the Respondent presented in his testimony before me, would neither prove nor disprove that the Respondent lacked candor when he testified on March 13, 2017.³⁰

Many of the items of testimony are not as clear cut as the Government suggests. For example, there is no evidence in the record concerning the number of Suboxone patients the Respondent treats. When asked multiple times, the Respondent consistently testified that he treats between 90–100 patients. Tr. 216, 275-78. While Government counsel made the statement, “I don’t believe that’s actually the case. I believe you’re treating less than that,” Tr. 278, the Government presented no evidence as to the number of Suboxone patients the Respondent is treating. This issue raised by the Government does not demonstrate any lack of candor, and the number is totally irrelevant to these proceedings. In fact when Government counsel was given the opportunity to proffer the relevance of this information, all he said was, “I was just going to credibility of the witness . . .” Tr. 279.

With respect to the issue of whether the Respondent ever bartered his medical services, my understanding of the testimony was that he had done that in the past, but he would not do it again because it is considered unethical. Tr. 250. Furthermore, whether he did or did

²⁹ The Government has provided no explanation of why it alleged that the Respondent produced the family records “several days” after having told investigators that he did not have any, when in fact they were produced about 18 months later after the documents were subpoenaed. A fair reading of the OSC suggests that something sinister was afoot by denying the existence of the documents but then producing them only several days later. The OSC suggests a linkage between the denial and quick turn-around time. The record does not support that conjecture.

³⁰ For example, it is possible that the Respondent was lacking in candor during his prior testimony, rather than during the March 13, 2017 hearing. He also could have just been confused. Further, there is no evidence in this Administrative Record that the Respondent’s March 15, 2016 deposition, Tr. 280, was taken in any sort of DEA proceeding or court proceedings that involved the DEA.

not barter in the past is not relevant to the issues before me. There is no lack of candor concerning this irrelevant issue.

The Government has made much of the Respondent's exact wording when he discussed benzodiazepines with [M.J.] and [P.L.]. Nevertheless, the Respondent admitted during the hearing that he had made a comparison between benzodiazepine and oxycodone, stating that oxycodone was more addictive. Tr. 253. He also testified that at the time he met with [M.J.] and [P.L.] he was of the impression that "benzodiazepines were not being abused and diverted." Tr. 238. During the Government's cross-examination of the Respondent on this subject, I did not find any lack of candor regarding this issue.

The Government incorrectly characterizes the Respondent's testimony about whether the Respondent would prescribe controlled substances to a patient who told the Respondent that he was giving some of the controlled substances to another individual. My review of the record leads me to the conclusion that the Respondent testified that he would not do that now, not what he may have done in the past. The record is not clear what question may have been asked at an earlier deposition concerning this peripheral issue. Tr. 285-88. I find no lack of candor.

Finally, the Government suggests that the Respondent lacked candor when he testified concerning whether he had ever taken "drugs" home to give to family members. In context, I find no relevance to any answers to this line questioning, particularly concerning the issues before me. First, the Respondent was not on notice of this issue and the question did not deal with controlled substances; rather, the Respondent was asked about "drugs". Second, I do not find a lack of candor because the Respondent essentially testified that he did not remember if he had taken drugs home to give to a family member, and then acknowledged that an earlier deposition indicated that he "may have taken drugs home." Tr. 290-91 (emphasis added).

Earlier in this decision I assessed the Respondent's credibility at length. Upon further review, specifically considering the Government's allegation that the Respondent lacked candor during his testimony, I reemphasize my earlier finding. When assessing the Respondent's credibility, I find that the clear and confident manner in which the Respondent testified on direct examination outweighs the manner in which he testified on cross examination. Further, when comparing his testimony

to that of other witnesses, I find that it was generally consistent with that of the Government's witnesses. Thus, I find that the Respondent's testimony to be generally credible. Accordingly, the Government's allegation, raised in its Post Hearing Brief, that the Respondent's testimony at the hearing demonstrated a lack of candor is **NOT SUSTAINED**.

DISCUSSION

Factors One and Three neither weigh for or against revocation in this case. As discussed, the Government did not present sufficient evidence of any other conduct the Respondent may have engaged in that may threaten the public health and safety. Accordingly, Factor Five does not weigh in favor of revocation. However, Factors Two and Four strongly weigh in favor of revoking the Respondent's COR because of his improper recordkeeping, and improper prescribing to himself, his family members, and his patients. Considering the public interest factors in their totality, I find that the Government has made a *prima facie* case showing that the Respondent's registration would be inconsistent with the public interest.

After the Government presents a *prima facie* case for revocation, the Respondent has the burden of production to present "sufficient mitigating evidence" to show why he can be entrusted with a DEA registration. See *Medicine Shoppe—Jonesborough*, 73 Fed. Reg. 364, 387 (2008) (quoting *Samuel S. Jackson, D.D.S.*, 72 Fed. Reg. 23848, 23853 (2007)). To rebut the Government's *prima facie* case, the Respondent must both accept responsibility for his actions and demonstrate that he will not engage in future misconduct. *Patrick W. Stodola, M.D.*, 74 Fed. Reg. 20727, 20734–35 (2009).

The Respondent may accept responsibility by providing evidence of his remorse, his efforts at rehabilitation, and his recognition of the severity of his misconduct. See *Robert A. Leslie, M.D.*, 68 Fed. Reg. 15227, 15228 (2003). To accept responsibility, a respondent must show "true remorse" for wrongful conduct. *Michael S. Moore, M.D.*, 76 Fed. Reg. 45867, 45877 (2011). An expression of remorse includes acknowledgment of wrongdoing. See *Wesley G. Harline, M.D.*, 65 Fed. Reg. 5665, 5671 (2000). A respondent must express remorse for all acts of documented misconduct, *Jeffrey Patrick Gunderson, M.D.*, 61 Fed. Reg. 26208, 26211 (1996), and may be required to acknowledge the scope of his misconduct, *Arvinder Singh, M.D.*, 81 Fed. Reg. 8247, 8250–51 (2016).

Acceptance of responsibility and remedial measures are assessed in the context of the "egregiousness of the violations and the [DEA's] interest in deterring similar misconduct by [the] Respondent in the future as well as on the part of others." *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38364 (2013).

Here, the Government accurately argued in its Post-Hearing Brief that "[t]he record contains no evidence that Respondent has actually accepted responsibility for the misconduct at issue in these proceedings and this is fatal to his cause." ALJ-37, at 23. While the Respondent admitted to many of the facts that support the allegations against him, he failed to fully accept responsibility for the most egregious aspects of his actions. Specifically, the Respondent failed to acknowledge that his prescribing and dispensing practices fell below the standard of care in the State of Connecticut. FF 62. Furthermore, the Respondent refused to admit that the prescriptions that he issued or dispensed to himself, his family, and his patients were issued or dispensed for other than legitimate medical purposes and outside the course of professional practice, despite being provided the opportunity to do so.³¹ Tr. 264-66. I find, however, that by

³¹ Additionally, the Government requests that I draw an adverse inference against the Respondent, with respect to his admission of responsibility, because the Respondent invoked his Fifth Amendment rights when asked by Government counsel if his actions were outside the course of professional practice. ALJ-37, at 26. It is well settled that at a DEA administrative hearing, it is permissible to draw an adverse inference from a respondent's failure "to testify in response to probative evidence offered against" him. *Darryl J. Mohr, M.D.*, 77 Fed. Reg. 34998, 35001 (2012) (citing *Baxter v. Palmigiano*, 425 U.S. 308, 316 (1976)). The Respondent argues that I should not draw a negative inference here because, unlike cases cited to by the Government, the Respondent did not refuse to testify, but just refused to answer questions that the Respondent argues called for a legal conclusion. ALJ-38, at 26. However, in *Mohr*, the registrant, offered testimony at hearing only in regards to his prescribing to K.R., an undercover patient. *Mohr*, 77 Fed. Reg. at 35000. Dr. Mohr offered no testimony as to why he prescribed to K.R. and also offered no testimony addressing his medical justification for prescribing a controlled substance to B.K., another undercover patient. *Id.* at 35001. Based on Dr. Mohr's failure to address why he prescribed to both patients, the Administrator found it "appropriate to draw the adverse inference that [Dr. Mohr] knowingly prescribed controlled substances to both B.K. and K.R. without a legitimate medical purpose." *Id.* Accordingly, based on the Respondent's unwillingness to acknowledge that his prescribing of controlled substances was outside the course of professional conduct, it is appropriate to draw the adverse inference that the Respondent did not accept responsibility for the allegations set for in paragraphs 7 and 9 of the OSC and which are supported by a preponderance of the evidence. See *MacKay v. DEA*, 664 F.3d 808, 820 (10th Cir. 2011) (holding that it was not "improper for the Deputy

entering into Stip. of Fact 4-21 the Respondent accepted responsibility for his recordkeeping violations that occurred in his practice prior to February 2014, as alleged in paragraph 4 of the OSC. FF 24. This limited acceptance of responsibility is outweighed by his numerous prescribing and dispensing transgressions, for which he has not accepted responsibility.³² See *Hatem M. Ataya, M.D.*, 81 Fed. Reg. 8221, 8244 (2016) (“[T]here are cases in which, notwithstanding a finding that a registrant has credibly accepted responsibility, the misconduct is so egregious and extensive that the protection of the public interest nonetheless warrants the revocation of a registration or the denial of an application.”).

When considering whether the Respondent’s continued registration is consistent with the public interest, the ALJ must consider both the egregiousness of the registrant’s violations and the DEA’s interest in deterring future misconduct by both the registrant as well as other registrants. *David A. Ruben, M.D.*, 78 Fed. Reg. 38363, 38364 (2013); see also *Richard J. Settles, D.O.*, 81 Fed. Reg. 64940, 64945 n.17 (2016) (“In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant’s misconduct.” (quoting *Jayam Krishna-Iyer, M.D.*, 74 Fed. Reg. 459, 462 (2009)). While I do not believe that the Respondent’s transgressions rise to the level of intentional or knowing diversion, I do find his multiple and repeated recordkeeping and prescribing violations to be sufficiently egregious to warrant revocation.³³ See *Dewey C.*

Administrator to draw an adverse inference from [the Respondent’s] failure to testify”). I note, however, that even absent the adverse inference, there is sufficient evidence to support the conclusion that the Respondent has not accepted responsibility for his improper prescribing and dispensing of controlled substances.

³² Although the Respondent also stipulated to many of the facts underlying the allegations contained in paragraphs 7 and 9 of the OSC, those stipulations do not admit to any misconduct. They just admit to facts. The essence of the allegations contained in paragraphs 7 and 9 of the OSC is that the Respondent’s actions involving controlled substances were outside the course of professional practice and furthered no legitimate medical purposes.

³³ I acknowledge that the Respondent has taken some remedial steps to reduce the likelihood that his actions would result in future violations of the CSA and/or its implementing regulations. Nevertheless, a registrant does not accept

MacKay, M.D., 75 Fed. Reg. 49956, 49974 n.35 (2010) (“[U]nder the public interest standard, DEA has authority to consider those prescribing practices of a physician, which, while not rising to the level of intentional or knowing misconduct, nonetheless create a substantial risk of diversion.”).

RECOMMENDATION

The Government established that the Respondent’s continued registration is inconsistent with the public interest because of his improper recordkeeping and improper prescribing, and/or dispensing, of controlled substances to himself, his family, and his patients. While the Respondent admitted to many of the Government’s factual allegations, he failed to fully accept responsibility and acknowledge that his egregious actions fell below the standard of care in the State of Connecticut, and/or lacked any legitimate medical purpose. Accordingly, I **RECOMMEND** that the Respondent’s DEA COR be **REVOKED** and that any application for renewal of his registration be **DENIED**.

Dated: May 25, 2017
s/Charles Wm. Dorman
U.S. Administrative Law Judge

CERTIFICATE OF SERVICE

This is to certify that the undersigned, on May 25, 2017, caused a copy of the foregoing to be transmitted via facsimile and placed in interoffice mail addressed to Paul A. Dean, Esq., Office of Chief Counsel, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; facsimile (202) 307-4946, and a copy to be transmitted via facsimile and mailed, postage prepaid, to counsel for the Respondent, Ronald W. Chapman, II, Esq. and Robert J. Andretz, Esq., 1441 West Long Lake Road, Suite 310, Troy, Michigan 48098; facsimile (248) 644-6324.

Rhonda L. Gore
Secretary to Judge Charles Wm. Dorman
Office of Administrative Law Judges

[FR Doc. 2019-02865 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

responsibility for its actions simply by taking remedial measures. *Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 & 5195*, 77 Fed. Reg. 62316, 62346 (2012). Further, where a registrant has not accepted responsibility it is not necessary to consider evidence of the registrant’s remedial measures. *Jones Total Health Care Pharmacy, L.L.C. & SND Health Care, L.L.C.*, 81 Fed. Reg. 79188, 79202-03 (2016).

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Navinta LLC

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 22, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been delegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on September 13, 2018, Navinta, LLC., 1499 Lower Ferry Road, Ewing, New Jersey 08618-1414 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Pentobarbital	2270	II
4-Anilino-N-phenethyl-4-piperidine (ANPP).	8333	II
Levorphanol	9220	II
Remifentanil	9739	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers.

Dated: February 11, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02877 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Noramco, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before April 22, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on October 30, 2018, Noramco, Inc., 500 Swedes Landing Road, Wilmington, Delaware 19801 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols.	7370	I
Codeine-N-oxide	9053	I
Dihydromorphine	9145	I
Hydromorphinol	9301	I
Morphine-N-oxide	9307	I
Amphetamine	1100	II

Controlled substance	Drug code	Schedule
Methylphenidate	1724	II
Nabilone	7379	II
Phenylacetone	8501	II
Codeine	9050	II
Dihydrocodeine	9120	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract ...	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Opium, granulated	9640	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Tapentadol	9780	II

The company plans to manufacture bulk active pharmaceutical ingredients (APIs) and reference standards for distribution to their customers.

In reference to drug codes 7360 (marihuana) and 7370 (tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetics. No other activities for these drug codes are authorized for this registration.

Dated: February 11, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02883 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Stepan Company

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 25, 2019. Such persons may also file a written request for a hearing on the application on or before March 25, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his

authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (“Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on December 7, 2018, Stepan Company, 100 W Hunter Ave, Maywood, New Jersey 07607, re-applied to be registered as a bulk manufacturer of the following basic classes of controlled substances.

Controlled substance	Drug code	Schedule
Cocaine	9041	II
Ecgonine	9180	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Dated: February 11, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02878 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and been granted registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of various classes of schedule I and II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on a previously published notice is listed below. No comments or objections were submitted for the notice.

Company	FR docket	Published
Chattem Chemicals	83 FR 56103	November 9, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a

registration as a bulk manufacturer to the above listed company.

Dated: January 29, 2019.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2019-02867 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: The registrant listed below has applied for and been granted registration by the Drug Enforcement Administration (DEA) as a bulk manufacturer of various classes of schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The company listed below applied to be registered as a bulk manufacturer of various basic classes of controlled substances. Information on a previously published notice is listed below. No comments or objections were submitted for the notice.

Company	FR docket	Published
Janssen Pharmaceuticals, Inc	83 FR 55205	November 2, 2018.

The DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of this registrant to manufacture the applicable basic classes of controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated the company's maintenance of effective controls against diversion by inspecting and testing the company's physical security systems, verifying the company's compliance with state and local laws, and reviewing the company's background and history.

Therefore, pursuant to 21 U.S.C. 823(a), and in accordance with 21 CFR 1301.33, the DEA has granted a

registration as a bulk manufacturer to the above listed company.

Dated: January 7, 2019.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2019-02868 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by the Drug Enforcement Administration (DEA) as importers of schedule I or schedule II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on the previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
Mylan Pharmaceuticals, Inc	83 FR 64158	December 13, 2018.
Siegfried USA, LLC	83 FR 64158	December 13, 2018.

The DEA has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each of the company's maintenance of effective controls

against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted registrations as importers for schedule II controlled substances to the above listed companies.

Dated: January 29, 2019.
John J. Martin,
Assistant Administrator.
 [FR Doc. 2019-02874 Filed 2-20-19; 8:45 am]
BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA-392]

Bulk Manufacturer of Controlled Substances Application: Research Triangle Institute**ACTION:** Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before March 25, 2019. Such persons may also file a written request for a hearing on the application on or before March 25, 2019.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division ("Assistant Administrator") pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.34(a), this is notice that on June 25, 2018, Research Triangle Institute, 3040 East Cornwallis Road, Hermann Bldg., Room 106, Research Triangle Park, North Carolina 27709, re-applied to be registered as a bulk manufacturer of small quantities of Tetrahydrocannabinols (7370), a basic class of a controlled substance listed in schedule I.

The company will manufacture via synthesis Tetrahydrocannabinols (7370), for use by researchers as Active Pharmaceutical Ingredients (API) for clinical trials.

Dated: January 29, 2019.

John J. Martin,

Assistant Administrator.

[FR Doc. 2019-02881 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-0296]

Agency Information Collection Activities: Proposed Collection; Comments Requested; Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired: 2018 Census of Medical Examiner and Coroner Offices (CMEC)**AGENCY:** Department of Justice.**ACTION:** 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics (BJS), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, Volume 83, Number 238, page 63909 on Wednesday, December 12, 2018. Following publication of the 60-day notice, the Bureau of Justice Statistics received no comments on the proposed collection.

DATES: Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Connor Brooks, Statistician, Law Enforcement Statistics Unit, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Connor.Brooks@usdoj.gov; phone: 202-514-8633). Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to OIRA_submissions@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Reinstatement of the Census of Medical Examiner and Coroner Offices, with changes, of a previously approved collection for which approval has expired.

(2) *The Title of the Form/Collection:* 2018 Census of Medical Examiner and Coroner Offices.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number is CMEC-1. The applicable component within the Department of Justice is the Bureau of Justice Statistics, Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

This information collection is a census of medical examiner and coroner offices. The 2018 survey is revised from the data collection referencing 2004. Respondents will be the medical examiners and coroners (or members of their staff) working in medicolegal death investigation offices.

Abstract: The 2018 CMEC will focus on the same topics as the 2004: The number and type of medical examiner and coroner offices operating in the U.S., staff at these offices, budget and capital resources, workload, policies and procedures regarding casework, specialized death investigations, records and evidence retention, resources, and operations. The survey was assessed by a panel of practitioners and subject matter experts. Results from these efforts were used to revise the survey to ensure content was up-to-date and relevant to the medicolegal death investigation system today. The survey was also revised to improve clarity and ease of answering questions. Suggestions resulting from this review were incorporated into the survey and

then cognitively tested with 14 medical examiner and coroner offices.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* A projected 2,200 respondents will take an average of 1.5 hours each to complete form CMEC-1, including time to research or find information not readily available. In addition, an estimated 1,100 respondents will be contacted for data quality follow-up by phone at 15 minutes per call.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 3,575 total burden hours associated with this information collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-02992 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF JUSTICE

[OMB Number 1117-0008]

Agency Information Collection Activities; Proposed eCollection, eComments Requested; Extension Without Change of a Previously Approved Collection; Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine; DEA Form 250

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), is submitting the following information collection request to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection was previously published in the **Federal Register**, on December 14, 2018, allowing for a 60-day comment period. **DATES:** Comments are encouraged and will be accepted for 30 days until March 25, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, especially on the estimated public

burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrisette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812. Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, Washington, DC 20503, or sent to OIRA_submission@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information proposed to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Application for Procurement Quota for Controlled Substance and for Ephedrine, Pseudoephedrine, and Phenylpropanolamine.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* DEA Form 250. The applicable component within the Department of Justice is the Drug Enforcement Administration, Diversion Control Division.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Affected public (Primary): Business or other for-profit.

Affected public (Other): None.

Abstract: Pursuant to 21 U.S.C. 826 and 21 CFR 1303.12(b) and 1315.32, any person who desires to use, during the next calendar year, any basic class of controlled substances listed in schedules I or II, or the List I chemicals ephedrine, pseudoephedrine, or phenylpropanolamine for purposes of manufacturing must apply on DEA Form 250 for a procurement quota for such class or List I chemical.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The DEA estimates 344 respondents complete 3,066 DEA Form 250 applications annually, and that each form requires 0.5 hours to complete.

6. *An estimate of the total public burden (in hours) associated with the proposed collection:* The DEA estimates this collection takes a total of 1,533 annual burden hours.

If additional information is required, please contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, Suite 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-03002 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

[OMB Number 1121-NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection: Methodological Research To Support the National Crime Victimization Survey Redesign Program: National Survey of Crime and Safety—Field Test

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 22, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jennifer Truman, Statistician, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Jennifer.Truman@usdoj.gov; telephone: 202-514-5083).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection under activities related to the National Crime Victimization Survey Redesign Program: National Survey of Crime and Safety—Field Test.

(2) *The Title of the Form/Collection:* National Survey of Crime and Safety (NSCS).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the questionnaire is NSCS1, NSCS2, NSCS3, NSCS4, NSCS5, and NSCS6. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief*

abstract: Respondents will be all persons 12 years or older living in households located throughout the 48 contiguous states and the District of Columbia sampled for the National Survey of Crime and Safety. Persons living in Alaska and Hawaii and those living in group quarters are excluded for operational efficiency. In early 2014, BJS initiated the NCVS Instrument Redesign and Testing Project to develop a new design for the NCVS. The overarching objective for this project is to redesign and test the NCVS roster control card, crime screener, and crime incident report. The purpose of the National Survey of Crime and Safety field test will be to test the redesigned versions of the roster control card, crime screener, and crime incident report. The NSCS field test will include administration of the current NCVS interview, an interviewer-administered, Web-based, revised questionnaire, and a self-administered version of the revised questionnaire. The goal of the NSCS field test is to inform final decisions and recommendations for the redesign of the NCVS survey instrument to modernize it and to capture indicators of safety, security and perceptions of police that provide important information on public perceptions and potential correlates of victimization.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimate of the total number of respondents is 12,293 persons age 12 or older. The sample is divided into three groups by instrument version: The current interviewer-administered NCVS instrument (NSCS1 and NSCS2), an interviewer-administered, Web-based, revised questionnaire (NSCS3 and NSCS4, and a self-administered version of the revised questionnaire (NSCS5 and NSCS6).

- The first group of 4,085 persons age 12 or older will receive the current interviewer-administered NCVS instrument. About 2,774 respondents will be the household respondent and receive the roster control card, which is estimated to take 9 minutes per respondent for a total of 416 burden hours. All 4,085 persons age 12 or older will receive the victimization screener, which is estimated to take 9 minutes per respondent for a total of 613 burden hours. It is anticipated that 768 persons in this group will report a victimization and receive the crime incident report, which is estimated to take 15 minutes per respondent for a total of 250 burden hours. There are an estimated 1,278 total burden hours for this group.

- The second group of 4,085 persons age 12 or older will receive the interviewer-administered Web-based, revised questionnaire. About 2,774 respondents will be the household respondent and receive the roster control card, which is estimated to take 9 minutes per respondent for a total of 416 burden hours. All 4,085 persons age 12 or older will receive the non-crime questions (perceptions of community safety or their local police) and victimization screener, which is estimated to take 16.2 minutes per respondent for a total of 1,103 burden hours. It is anticipated that 768 persons in this group will report a victimization and receive the crime incident report, which is estimated to take 18 minutes per respondent for a total of 300 burden hours. There are an estimated 1,819 total burden hours for this group.

- The third group of 4,122 persons age 12 or older will receive the self-administered version of the revised questionnaire. About 3,752 respondents will be the household respondent and receive the roster control card, which is estimated to take 9 minutes per respondent for a total of 563 burden hours. All 4,122 persons age 12 or older will receive the non-crime questions (perceptions of community safety or their local police) and victimization screener, which is estimated to take 13.2 minutes per respondent for a total of 907 burden hours. It is anticipated that 768 persons in this group will report a victimization and receive the crime incident report, which is estimated to take 15 minutes per respondent for a total of 250 burden hours. There are an estimated 1,719 total burden hours for this group.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 4,816 burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019-02991 Filed 2-20-19; 8:45 am]

BILLING CODE 4410-18-P

DEPARTMENT OF JUSTICE

[OMB Number 1121–NEW]

Agency Information Collection Activities; Proposed Collection Comments Requested; New Collection: Survey of Law Enforcement Personnel in Schools (SLEPS)**AGENCY:** Bureau of Justice Statistics, Department of Justice.**ACTION:** 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until April 22, 2019.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Elizabeth Davis, Statistician, Law Enforcement Statistics, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: Elizabeth.Davis@usdoj.gov; telephone: 202–305–2667).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g.,

permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *The Title of the Form/Collection:* Survey of Law Enforcement Personnel in Schools (SLEPS).

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form number for the agency survey is SLEPS–1; the form number for the officer survey is SLEPS–2. The applicable component within the Department of Justice is the Bureau of Justice Statistics, in the Office of Justice Programs.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will be law enforcement agencies (LEAs), including school-based police; municipal, county, and regional police; sheriff's offices; and school resource officers (SROs) employed by these LEAs.

SLEPS will examine law enforcement involvement in ensuring safety in schools by conducting both an agency-level and an officer-level survey. The agency-level survey asks about departmental policies and agreements with schools; funding sources and the number/type of schools served; and SRO recruitment, training, and supervision. The officer-level survey asks SROs about their experience as a law enforcement officer, training, activities in schools, and characteristics of their primary assignment. SLEPS will provide key national statistics to fill the knowledge gap surrounding law enforcement in schools and further the school safety agenda.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An agency-level survey will be sent to approximately 1,982 LEA respondents. The expected burden placed on these respondents is about 30 minutes per respondent. These respondents will also receive an officer roster form which has an expected burden of about 10 minutes per respondent. It is expected that approximately 1,367 agencies will complete the roster form. A point of contact (POC) at these 1,367 agencies will be asked to distribute an officer-level survey to approximately 4,137 school resource officers. The expected burden is about 20 minutes per POC to distribute survey materials and about 30 minutes per officer to complete the survey.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total respondent burden is approximately 3,743 burden hours.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: February 15, 2019.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2019–02993 Filed 2–20–19; 8:45 am]

BILLING CODE 4410–18–P**DEPARTMENT OF LABOR****Employment and Training Administration****Agency Information Collection Activities; Comment Request; Apprenticeship Powered by Industry (API) Data Collection****ACTION:** Notice.

SUMMARY: The Department of Labor's (DOL's), Employment and Training Administration (ETA) is soliciting comments concerning proposed authority to conduct the voluntary information collection request (ICR) titled, "Apprenticeship Powered by Industry (API) Data Collection." This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by April 22, 2019.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Carolyn Renick by telephone at 202–693–3364 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at renick.carolyn.g@dol.gov.

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Apprenticeship, Room C–5311, 200 Constitution Avenue NW, Washington, DC 20210; by email: renick.carolyn.g@dol.gov; or by Fax (202) 693–3799.

FOR FURTHER INFORMATION CONTACT: Carolyn Renick by telephone at 202–693–3364 (this is not a toll-free number) or by email at renick.carolyn.g@dol.gov.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The information collection described in this notice will provide data to (1) estimate the number of business establishments that currently operate apprenticeship and apprenticeship-like earn-and-learn programs across industry groups, and (2) document descriptive information on these existing programs. This research is in direct response to Executive Order 13801, “Expanding Apprenticeships in America” (www.whitehouse.gov/presidential-actions/3245/), as well as the Secretary of Labor and the Office of Apprenticeship’s efforts to promote and expand apprenticeship and to establish Industry-Recognized Apprenticeship Programs (IRAPs).

The information collection activities include a brief five- to 10-minute survey of businesses that will gather information on any existing apprenticeship and apprenticeship-like earn-and-learn programs they operate. In addition to the survey, the study includes follow-up interviews with a purposive sample of businesses identified as having apprenticeship-like programs through the survey. The interview protocol will be used to gather more detailed, in-depth information on the existing programs, including the types of participants they serve, the skills they address, the certifications they provide, as well as how the businesses work with organizations to accredit the programs. The interview protocol will also inquire about businesses’ training decisions and experiences.

This **Federal Register** Notice provides the opportunity to comment on these two proposed data collection instruments. Additional details on each are presented below.

■ **Business Survey.** Researchers will field a brief five- to 10-minute web-based survey of businesses that will gather information on any existing work-based learning programs they operate. Businesses that prefer to do so will be able to complete the survey over the phone.

■ **Business Follow-up Interview Protocol.** Researchers will conduct half-hour phone interviews with a purposive sample of up to 120 businesses identified as having apprenticeship-like programs through the business survey.

Executive Order 13801, “Expanding Apprenticeships in America” authorizes this information collection.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention 1205–0NEW.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who 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).

Agency: DOL–ETA.

Type of Review: New.

Title of Collection: Apprenticeship Powered by Industry (API) Data Collection.

Form: 1. Business Survey; 2. Follow-up Business Interview Protocol.

OMB Control Number: 1205–0NEW.

Affected Public: Businesses.

Estimated Number of Respondents: 6,840.

Frequency: Once.

Total Estimated Annual Responses: 6,840.

Estimated Average Time per Response: Varies (Survey 6.5 minutes; Interview 30 minutes).

Estimated Total Annual Burden

Hours: 788 hours.

Total Estimated Annual Other Cost Burden: \$0.

Molly E. Conway,

Acting Assistant Secretary for Employment and Training.

[FR Doc. 2019–02994 Filed 2–20–19; 8:45 am]

BILLING CODE 4510–FR–P

LIBRARY OF CONGRESS

Copyright Royalty Board

[Docket No. **CONSOLIDATED 14–CRB–0010–CD (2010–2013)**]

Distribution of Cable Royalty Funds

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Final allocation determination; correction.

SUMMARY: The Copyright Royalty Judges published a document in the **Federal Register** of February 12, 2019, concerning allocation of cable royalty funds. The document contained an incorrect reference to satellite royalty funds in the Summary and was missing citations in four footnotes.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, by phone at (202) 707–7658 or by email at crb@loc.gov.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 12, 2019, in FR Doc. 2019–01544, on page 3552, in the first column, correct the Summary to read: The Copyright Royalty Judges announce the allocation of shares of cable royalty funds for the

years 2010, 2011, 2012, and 2013 among six claimant groups. On page 3600, in the third column, correct footnote 169 to read: *See* sections IV.C.3–IV.C.5. On page 3566, in the second column, correct footnote 61 to read: The Judges discussed the distinction between an “effects” regression and a “prediction” regression at length, *supra*, section II.B.2.j. On page 3588, in the second column, correct footnote 132 to read: *See* discussion at section III.D.2.b. On page 3604, in the first column, correct footnote 179 to read: The Judges discuss the relevant prior rulings, *infra*, section VII.B.5.

Dated: February 15, 2019.

Suzanne M. Barnett,

Chief United States Copyright Royalty Judge.

[FR Doc. 2019–02942 Filed 2–20–19; 8:45 am]

BILLING CODE 1410–72–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Physics; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces the following meeting:

Name and Committee Code: Mid-Term Site Visit to BaPSF for the Division of Physics (1208)—University of California—Los Angeles.

Date and Time: March 25, 2019; 8:00 a.m.–6:30 p.m.

Place: University of California, 1000 Veteran Ave, Los Angeles, CA 90024.

Type of Meeting: Closed.

Contact Person: Lukin Vyacheslav, Program Director for Plasma, Division of Physics, National Science Foundation, 2415 Eisenhower Avenue, Room W9218, Alexandria, VA 22314; Telephone: (703) 292–7382.

Purpose of Meeting: Site visit to provide an evaluation of the progress of the projects at the host site for the Division of Physics at the National Science Foundation.

Agenda

March 25, 2019; 8:00 a.m.–6:30 p.m.

8:00 a.m.–8:30 a.m. Executive Session (Closed)

8:30 a.m.–9:00 a.m. Overview

9:00 a.m.–9:45 a.m. Physics Topic 1

9:45 a.m.–10:15 a.m. Lab Tour

10:15 a.m.–10:30 a.m. Break

10:30 a.m.–11:15 a.m. Physics Topic 2

11:15 a.m.–11:45 a.m. Physics Topic 3

12:00 p.m.–12:30 p.m. Executive Session (Closed)

12:30 p.m.–1:15 p.m. Lunch with Students

1:15 p.m.–2:00 p.m. Physics Topic 4 (Co-PIs)

2:00 p.m.–2:45 p.m. Education Broader Impacts (PI and Co-PIs)

2:45 p.m.–3:15 p.m. Operations and Structure of Group (PI)

3:15 p.m.–3:45 p.m. Personnel Information (PI)

3:45 p.m.–4:15 p.m. Executive Session (Closed)

4:15 p.m.–4:45 p.m. Coffee with Collaborating Groups

4:45 p.m.–5:05 p.m. Executive Session with Dean and V.P. for Research

5:05 p.m.–6:05 p.m. Questions for PI’s

6:05 p.m.–6:30 p.m. Site Visitors and NSF Staff Dinner (Closed)

Reason for Closing: Topics to be discussed and evaluated during closed portions of the site review will include information of a proprietary or confidential nature, including technical information and information on personnel. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: February 14, 2019.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2019–02879 Filed 2–20–19; 8:45 am]

BILLING CODE 7555–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85142; File No. SR–CboeBZX–2019–008]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Clarify That BZX’s Halt Auction Process Is Applicable Only To Halt Auctions Following a Regulatory Halt

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on February 5, 2019, Cboe BZX Exchange, Inc. (the “Exchange” or “BZX”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a “non-controversial” proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b–4(f)(6) thereunder.⁴ The Commission is publishing this notice to

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b–4(f)(6).

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

Cboe BZX Exchange, Inc. (“BZX” or the “Exchange”) is filing with the Securities and Exchange Commission (the “Commission”) a proposed rule change to clarify that BZX’s Halt Auction process is applicable only to Halt Auctions following a Regulatory Halt. The text of the proposed rule change is attached [sic] as Exhibit 5.

The text of the proposed rule change is also available on the Exchange’s website (http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to clarify that BZX’s Halt Auction process is applicable only to Halt Auctions following a Regulatory Halt such as a material news halt, a trading halt following the initiation of the market wide circuit breaker mechanism, or a Trading Pause initiated pursuant to the Plan to Address Extraordinary Market Volatility—*i.e.*, the “Limit Up-Limit Down” or “LULD” Plan. On December 21, 2018, the Exchange filed a proposed rule change to amend the process for re-opening BZX listed securities following a Regulatory Halt.⁵ Specifically, the Exchange amended BZX Rule 11.23(d) to provide for a measured and transparent process for re-opening BZX listed securities after a Non-LULD

⁵ See Securities Exchange Act Release No. 34–84927 (December 21, 2018), 83 FR 67768 (December 31, 2018) (SR–CboeBZX–2018–090).

Regulatory Halt that mirrors the Halt Auction process already used by the Exchange following a Trading Pause initiated pursuant to the LULD Plan. As part of that rule filing, which became operative on January 20, 2019, the Exchange differentiated for the first time between the process to be used for Halt Auctions following a Regulatory Halt and the process that would continue to be used for IPO Auctions and Halt Auctions following a Non-Regulatory Halt. In practice, however, Halt Auctions are not conducted in situations where the Exchange has determined to re-open trading in BZX listed securities following a Non-Regulatory Halt. In such rare instances where the Exchange suspends trading for non-regulatory reasons, such as due to a technical or systems issue that is limited to trading on BZX, the Exchange re-opens trading without an auction.

The Exchange therefore proposes to amend its rules to eliminate mistaken references to Halt Auctions following a Non-Regulatory Halt, as described herein. First, BZX Rule 11.23(d) provides that the Exchange will conduct an IPO Auction or Halt Auction for trading in a BZX listed security in an IPO or following a trading halt in that security. The Exchange proposes to amend this rule to instead provide that BZX Rule 11.23(d) applies to trading in a BZX listed security in an IPO or following a Regulatory Halt in that security. The Exchange believes that specifying in BZX Rule 11.23(d) that the Halt Auction process applies specifically to Regulatory Halts, rather than the more generic trading halt, would reduce potential confusion about when a Halt Auction is initiated. Second, the Exchange proposes to amend portions of BZX Rules 11.23(d)(2)(B) and (E) to remove incorrect references to Halt Auctions following a Non-Regulatory Halt. As proposed, BZX rule 11.23(d)(2)(B) would be amended to provide that this paragraph describes the process for extending the Quote-Only Period for IPO Auctions. In addition, BZX rule 11.23(d)(2)(B)(ii) would be amended to remove the reference to IPO Auctions in that subsection since all of BZX Rule 11.23(d)(2)(B) would be limited to such auctions. Furthermore, BZX Rule 11.23(d)(2)(E) would be amended to provide that, for IPO Auctions only, rather than IPO Auctions and Halt Auctions following a Non-Regulatory Halt, orders will be executed at the price level within the Collar Price Range that maximizes the number of shares executed in the auction. These changes would properly reflect the current

operation of the Exchange by stating that certain functionality applies specifically to IPO Auctions, rather than to both IPO Auctions and Halt Auctions following a Non-Regulatory Halt.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,⁶ in general, and Section 6(b)(5) of the Act,⁷ in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest and not to permit unfair discrimination between customers, issuers, brokers, or dealers. Specifically, the Exchange believes that the proposed rule change is consistent with the protection of investors and the public interest as it is designed to increase transparency around the operation of Halt Auctions in BZX listed securities.

The Exchange recently filed a proposed rule change to amend its Halt Auction process used to re-open BZX listed securities following a Regulatory Halt. The amended rules, which became operative on January 20, 2019, suggest that the Exchange's Halt Auction process is used to re-open securities following either a Regulatory Halt or a Non-Regulatory Halt. While the substance of that proposed rule change to amend the process for re-opening BZX listed securities following a Non-LULD Regulatory Halt is accurate, the changes that referenced Halt Auctions following a Non-Regulatory Halt were made in error as the Exchange only uses the Halt Auction process to re-open trading in BZX listed securities following a Regulatory Halt. Since a Halt Auction is unnecessary to pool liquidity following a Non-Regulatory Halt, and indeed could be disruptive where continuous trading has continued on other equities markets, the Exchange does not use its auction process following such halts. Instead, the Exchange immediately transitions into continuous trading by entering remaining orders into the BZX Book after the halt is ended and trading can resume. The proposed rule change would correct BZX Rule 11.23(d) to specify that Halt Auctions are only initiated after a Regulatory Halt, and make related changes, such as eliminating incorrect references to Halt Auctions following a Non-Regulatory Halt. The proposed amendments to the

Halt Auction rules would therefore serve to ensure that the Exchange's rules are clear and accurate. No changes to the Exchange's systems or procedures are contemplated by this proposed rule change.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to correct erroneous references in BZX Rule 11.23(d) to Halt Auctions following a Non-Regulatory Halt, and clarify that BZX's Halt Auction process is applicable only to Halt Auctions following a Regulatory Halt. As a result, the Exchange believes that the proposed rule change will have no impact on competition but will rather serve to reduce potential confusion about when a Halt Auction is initiated.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act⁸ and subparagraph (f)(6) of Rule 19b-4 thereunder.⁹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹⁰ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹¹ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked

⁶ 15 U.S.C. 78s(b)(3)(A).

⁹ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹⁰ 17 CFR 240.19b-4(f)(6).

¹¹ 17 CFR 240.19b-4(f)(6)(iii).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

the Commission to waive the 30-day operative delay so that the proposal may become operative upon filing. The Exchange states that waiver of the 30-day operative delay would allow the Exchange to immediately amend its rules to correct an error, thereby increasing transparency around the Exchange's use of the Halt Auction and ensuring that members and investors are appropriately apprised of the fact that this auction is limited to the resumption of trading following a Regulatory Halt, as has always been its practice. For these reasons, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.¹²

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 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:

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-CboeBZX-2019-008 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-CboeBZX-2019-008. This file number should be included on the subject line if email is used. To help the Commission process and review your

¹² For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

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-CboeBZX-2019-008 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹³

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02903 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85143; File No. SR-MRX-2019-02]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Pricing Schedule at Options 7, Section 3

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on January 31, 2019, Nasdaq MRX, LLC ("MRX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule

¹³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Pricing Schedule at Options 7, Section 3, entitled "Regular Order Fees and Rebates."

While these amendments are effective upon filing, the Exchange has designated the proposed amendments to be operative on February 1, 2019.

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqmrx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Pricing Schedule at Options 7, Section 3, entitled "Regular Order Fees and Rebates" at Table 2 to (1) amend PIM Fees for Crossing Orders³ for both Penny and Non-Penny Symbols; (2) increase Non-Penny Fees for Reponses to Crossing Orders; (3) adopt a letter "(c)" within Options 7, Section 1 for ease of reference to defined terms. The Exchange will describe each amendment below.

³ A "Crossing Order" is an order executed in the Exchange's Facilitation Mechanism, Solicited Order Mechanism, Price Improvement Mechanism ("PIM") or submitted as a Qualified Contingent Cross order. For purposes of this Pricing Schedule, orders executed in the Block Order Mechanism are also considered Crossing Orders.

Fees for Crossing Orders

Today, MRX assesses a Fee for Crossing Orders in Penny and Non-Penny Symbols of \$0.20 per contract for Market Maker,⁴ Non-Nasdaq MRX Market Maker,⁵ Firm Proprietary,⁶ Broker-Dealer,⁷ and Professional Customer⁸ orders, and \$0.00 per contract for Priority Customer Orders.⁹ These fees apply to both originating and contra-side orders for all Crossing Orders.

MRX proposes to continue assessing the Fees for Crossing Orders in Table 2 for Penny and Non-Penny Symbols with respect to originating PIM Orders. MRX proposes to assess a Fee for Crossing Orders in all symbols for PIM orders of \$0.05 per contract provided a market participant is on the contra-side of a PIM auction. This fee would apply to all market participants. This fee represents a reduced fee for Market Maker, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders (from \$0.20 to \$0.05 per contract) and an increased fee for Priority Customers (from \$0.00 to \$0.05 per contract).¹⁰

Further, MRX proposes to pay a rebate to an originating Priority Customer PIM Order that executes with a response (an order or quote), other than the PIM contra-side order, of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols. The Exchange believes that this proposal will encourage greater participation in PIM auctions.

The Exchange proposes to amend note 1 within the Pricing Schedule at Options 7, Section 3 to add “-side” after the term “contra” in the existing

⁴ A “Market Maker” is a market maker as defined in Nasdaq MRX Rule 100(a)(30). Market Maker fees discussed in this section also apply to Market Maker orders sent to the Exchange by Electronic Access Members.

⁵ A “Non-Nasdaq MRX Market Maker” is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange.

⁶ A “Firm Proprietary” order is an order submitted by a Member for its own proprietary account.

⁷ A “Broker-Dealer” order is an order submitted by a Member for a broker-dealer account that is not its own proprietary account.

⁸ A “Professional Customer” is a person or entity that is not a broker/dealer and is not a Priority Customer.

⁹ A “Priority Customer” is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Nasdaq MRX Rule 100(a)(37A).

¹⁰ MRX is not amending fees with respect to the Facilitation Mechanism, Solicited Order Mechanism, or an order submitted as a Qualified Contingent Cross order or an order executed in the Block Order Mechanism.

sentence. The Exchange also proposes to add the following text to that sentence, “. . . except for PIM Orders. With respect to PIM Orders, the Fees for Crossing Orders apply to PIM originating orders, however all market participants on the contra-side of a PIM auction will be assessed a Fee for Crossing Orders of \$0.05 per contract. An originating Priority Customer PIM Order that executes with any response (order or quote), other than the PIM contra-side order, will receive a rebate of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols.”

Fees for Responses to Crossing Orders

Today, MRX assesses a Fee for Responses to Crossing Orders of \$0.50 per contract in Penny Symbols to all market participants and \$0.95 per contract in Non-Penny Symbols to all market participants.

MRX proposes to increase the Fees for Responses to Crossing Orders in Non-Penny Symbols from \$0.95 to \$1.10 per contract for all market participants. No changes are proposed to Penny Symbols for Fees for Responses to Crossing Orders. The Exchange proposes to utilize the increased rate to offer rebates to Priority Customers who submit PIM Orders as described above.¹¹

Options 7, Section 1

The Exchange proposes to amend Options 7, Section 1 to add a letter “(c)” before certain defined terms for ease of reference.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,¹² in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹³ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange believes that the proposed changes will attract PIM order flow to MRX, which will create trading opportunities on MRX to the benefit of all Members.

¹¹ MRX proposes herein to pay a rebate to an originating Priority Customer PIM Order that executes with any response, other than the PIM contra-side order, of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols.

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(4) and (5).

Fees for Crossing Orders

The Exchange believes that its proposal to assess contra-side PIM Orders a reduced Fee for Crossing Orders in both Penny and Non-Penny Symbols of \$0.05 per contract instead of \$0.20 per contract to Market Maker, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders is reasonable because the Exchange proposes to encourage these market participants to submit a greater amount of order flow to the MRX PIM auction. The Exchange believes that it is reasonable to assess Priority Customers an increased \$0.05 per contract Fee for Crossing Orders¹⁴ for contra-side PIM Orders in Penny and Non-Penny Symbols because the Exchange is also offering Priority Customers an opportunity to receive a rebate of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols for any originating Priority Customer PIM Order that executes with any response, other than the PIM contra-side order. As is the case today, Priority Customers will not pay a Fee for Crossing Orders in Penny and Non-Penny Symbols with respect to originating PIM Orders and non-PIM Crossing Order transactions.

The Exchange believes that its proposal to assess contra-side PIM Orders a lower Fee for Crossing Orders in both Penny and Non-Penny Symbols of \$0.05 per contract instead of \$0.20 per contract to Market Maker, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders is equitable and not unfairly discriminatory because the Exchange will uniformly charge all market participants, except Priority Customers, a lower contra-side Fee for Crossing PIM Orders in Penny and Non-Penny Symbols. While a Priority Customer’s contra-side Fee for Crossing PIM Orders will increase from \$0.00 to \$0.05 per contract in both Penny and Non-Penny Symbols, the Priority Customer has an opportunity to receive a rebate of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols for any originating Priority Customer PIM Order that executes with any response, other than the PIM contra-side order. As is the case today, Priority Customers will not pay an originating Fee for PIM Orders. Further, the Exchange notes that Priority Customer interest brings valuable liquidity to the

¹⁴ Today, Priority Customers pay no Fee for Crossing Orders (originating or contra-side orders) with respect to PIM transactions in either Penny or Non-Penny Symbols.

market, which liquidity benefits other market participants. Priority Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

Fees for Responses to Crossing Orders

The Exchange believes that its proposal to increase the Non-Penny Symbol Fees for Responses to Crossing Orders from \$0.95 to \$1.10 per contract for all market participants is reasonable because while these fees are increasing the Exchange believes that the fees remain competitive and will continue to attract order flow to the Exchange. Further, the Exchange proposes to utilize the increased rate to offer rebates to Priority Customers who submit PIM Orders as described herein.¹⁵ Priority Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

The Exchange believes that its proposal to increase the Non-Penny Symbol Fees for Responses to Crossing Orders from \$0.95 to \$1.10 per contract for all market participants is equitable and not unfairly discriminatory because all market participants will be uniformly assessed the increased fee in Non-Penny Symbols.

Options 7, Section 1

The Exchange's proposal to amend Options 7, Section 1 to add a letter "(c)" before certain defined terms is reasonable, equitable and not unfairly discriminatory because this non-substantive amendment merely makes the section easier to reference.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange's proposal does not impose a burden on inter-market competition because the proposed fee structure for Crossing Orders remains competitive with other options exchanges. MRX operates in a highly competitive market

in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges. Because competitors are free to modify their own fees in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

Fees for Crossing Orders

The Exchange believes that its proposal to assess contra-side PIM Orders a lower Fee for Crossing Orders in both Penny and Non-Penny Symbols of \$0.05 per contract instead of \$0.20 per contract to Market Maker, Non-Nasdaq MRX Market Maker, Firm Proprietary, Broker-Dealer, and Professional Customer orders does not impose a burden on intra-market competition because the Exchange will uniformly pay all market participants, except Priority Customers, a lower contra-side Fee for Crossing PIM Orders in Penny and Non-Penny Symbols. While a Priority Customer's contra-side Fee for Crossing PIM Orders will increase from \$0.00 to \$0.05 per contract in Penny and Non-Penny Symbols, the Priority Customer has an opportunity to receive a rebate of \$0.40 per contract in Penny Symbols and \$1.00 per contract in Non-Penny Symbols for any originating Priority Customer PIM Order that executes with any response, other than the PIM contra-side order. As is the case today, Priority Customers will not pay an originating Fee for PIM Orders. Further, the Exchange notes that Priority Customer interest brings valuable liquidity to the market, which liquidity benefits other market participants. Priority Customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants.

Fees for Responses to Crossing Orders

The Exchange believes that its proposal to increase the Non-Penny Symbol Fees for Responses to Crossing Orders from \$0.95 to \$1.10 per contract for all market participants does not impose a burden on intra-market competition because all market

participants will be uniformly assessed the increased fee in Non-Penny Symbols.

Options 7, Section 1

The Exchange's proposal to amend Options 7, Section 1 to add a letter "(c)" before certain defined terms does not impose an undue burden on intra-market competition because this non-substantive amendment merely makes the section easier to reference.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.¹⁶ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MRX-2019-02 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-MRX-2019-02. This file number should be included on the subject line if email is used. To help the Commission process and review your

¹⁵ See note 9 above.

¹⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

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-MRX-2019-02 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019-02904 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85140; File No. SR-GEMX-2019-01]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Options Regulatory Fee

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 1, 2019, Nasdaq GEMX, LLC ("GEMX" or "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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to revise GEMX's Pricing Schedule to amend its Options Regulatory Fee or "ORF".

The text of the proposed rule change is available on the Exchange's website at <http://nasdaqgemx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Currently, GEMX assesses an ORF of \$0.0020 per contract side. The Exchange proposes to decrease this ORF to \$0.0018 per contract side as of February 1, 2019. GEMX proposes to decrease its ORF to ensure that regulatory revenues will not exceed regulatory costs. The Exchange's proposed change to the ORF should balance the Exchange's regulatory revenue against the anticipated regulatory costs. The Exchange also proposes to delete obsolete language in the rule text as described herein.

Collection of ORF

Currently, GEMX assesses its ORF for each customer option transaction that is either: (1) Executed by a Member on GEMX; or (2) cleared by a GEMX Member at The Options Clearing Corporation ("OCC") in the customer range,³ even if the transaction was

executed by a non-member of GEMX, regardless of the exchange on which the transaction occurs.⁴ If the OCC clearing member is a GEMX Member, ORF is assessed and collected on all cleared customer contracts (after adjustment for CMTA⁵); and (2) if the OCC clearing member is not a GEMX Member, ORF is collected only on the cleared customer contracts executed at GEMX, taking into account any CMTA instructions which may result in collecting the ORF from a non-member.

By way of example, if Broker A, a GEMX Member, routes a customer order to CBOE and the transaction executes on CBOE and clears in Broker A's OCC Clearing account, ORF will be collected by GEMX from Broker A's clearing account at OCC via direct debit. While this transaction was executed on a market other than GEMX, it was cleared by a GEMX Member in the member's OCC clearing account in the customer range, therefore there is a regulatory nexus between GEMX and the transaction. If Broker A was not a GEMX Member, then no ORF should be assessed and collected because there is no nexus; the transaction did not execute on GEMX nor was it cleared by a GEMX Member.

In the case where a Member both executes a transaction and clears the transaction, the ORF is assessed to and collected from that Member. In the case where a Member executes a transaction and a different member clears the transaction, the ORF is assessed to and collected from the Member who clears the transaction and not the Member who executes the transaction. In the case where a non-member executes a transaction at an away market and a Member clears the transaction, the ORF is assessed to and collected from the Member who clears the transaction. In the case where a Member executes a transaction on GEMX and a non-member clears the transaction, the ORF is assessed to the Member that executed the transaction on GEMX and collected from the non-member who cleared the transaction. In the case where a Member executes a transaction at an away market and a non-member clears the transaction, the ORF is not assessed to the Member who executed the transaction or collected from the non-member who cleared the transaction because the Exchange does not have access to the data to make absolutely

surveillances in place to verify that members mark orders with the correct account origin code.

⁴ The Exchange uses reports from OCC when assessing and collecting the ORF.

⁵ CMTA or Clearing Member Trade Assignment is a form of "give-up" whereby the position will be assigned to a specific clearing firm at OCC.

¹⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ Members must record the appropriate account origin code on all orders at the time of entry in order. The Exchange represents that it has

certain that ORF should apply. Further, the data does not allow the Exchange to identify the Member executing the trade at an away market.

ORF Revenue and Monitoring of ORF

The Exchange monitors the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange reviews all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter offset ORF.

The ORF is designed to recover a material portion of the costs to the Exchange of the supervision and regulation of its members, including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities.

The Exchange believes that revenue generated from the ORF, when combined with all of the Exchange's other regulatory fees, will cover a material portion, but not all, of the Exchange's regulatory costs. The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed regulatory costs. If the Exchange determines regulatory revenues exceed regulatory costs, the Exchange will adjust the ORF by submitting a fee change filing to the Commission.

Proposal

The Exchange proposes to decrease the ORF from \$0.0020 to \$0.0018 per contract side as of February 1, 2019 to ensure that regulatory expenses will not exceed regulatory costs. The Exchange proposes to add the following rule text to Options 7, Section 5, "GEMX Members will be assessed an Options Regulatory Fee of \$0.0018 per contract side as of February 1, 2019."

The Exchange regularly reviews its ORF to ensure that the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs. The Exchange believes this adjustment will permit the Exchange to continue to cover a material portion of its regulatory costs, while not exceeding regulatory costs.

The Exchange notified Members via an Options Trader Alert of the proposed change to the ORF thirty (30) calendar days prior to the proposed operative

date, February 1, 2019.⁶ The Exchange believes that the prior notification market participants are prepared to configure their systems to account properly for the ORF.

Finally, the Exchange proposes to remove the following rule text from Options 7, Section 5, "The ORF is \$0.0010 per contract side until July 31, 2018. \$0.0020 per contract side as of August 1, 2018". This text is obsolete as it references prior ORF rates which were effective in the past.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act⁷ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act⁸ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using its facility and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that decreasing the ORF from \$0.0020 to \$0.0018 per contract side as of February 1, 2019 is reasonable because the Exchange's collection of ORF needs to be balanced against the amount of regulatory costs incurred by the Exchange. The Exchange believes that the proposed adjustments noted herein will serve to balance the Exchange's regulatory revenue against the anticipated regulatory costs.

The Exchange believes that decreasing the ORF from \$0.0020 to \$0.0018 per contract side as of February 1, 2019 is equitable and not unfairly discriminatory because assessing the ORF to each Member for options transactions cleared by OCC in the customer range where the execution occurs on another exchange and is cleared by a GEMX Member is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. OCC collects the ORF on behalf of GEMX from Exchange clearing members for all customer transactions they clear or from non-members for all customer transactions they clear that were executed on GEMX. The Exchange believes the ORF ensures fairness by assessing fees to Members based on the amount of customer options business they conduct. Regulating customer trading activity is much more labor intensive and requires

greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (e.g., Member proprietary transactions) of its regulatory program.

The ORF is designed to recover a material portion of the costs of supervising and regulating Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. The Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, does not exceed the Exchange's total regulatory costs. The Exchange has designed the ORF to generate revenues that, when combined with all of the Exchange's other regulatory fees, will be less than or equal to the Exchange's regulatory costs, which is consistent with the Commission's view that regulatory fees be used for regulatory purposes and not to support the Exchange's business side.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. This proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from the ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

⁶ See Options Trader Alert #2018-46.

⁷ 15 U.S.C. 78f(b).

⁸ 15 U.S.C. 78f(b)(4) and (5).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.⁹ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File No. SR-GEMX-2019-01 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 No. SR-GEMX-2019-01. 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 No. SR-GEMX-2019-01, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019-02901 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85135; File No. SR-MSRB-2019-02]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Rule A-16, on Examination Fees, To Establish a Test Development Fee for the Series 54 Examination

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 11, 2019 the Municipal Securities Rulemaking Board ("MSRB") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the MSRB. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission a proposed rule change to amend Rule A-16, on examination fees, to establish a test development fee for the Municipal Advisor Principal Qualification Examination ("Series 54 examination") (the "proposed rule change"). The

MSRB has designated the proposed rule change for immediate effectiveness pursuant to Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b-4(f)(2)⁴ thereunder.

The text of the proposed rule change is available on the MSRB's website at www.msrb.org/Rules-and-Interpretations/SEC-Filings/2019-Filings.aspx, at the MSRB's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the MSRB included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The MSRB has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to establish a test development fee of \$150 for the new Series 54 examination to align with the MSRB's current test development fee of \$150 for each of its four existing professional qualification examinations.⁵ Section 15B of the Act authorizes the MSRB to prescribe "standards of training, experience, competence, and such other qualifications as the Board finds necessary or appropriate in the public interest or for the protection of investors and municipal entities or obligated persons"⁶ and requires persons in any such class to pass tests prescribed by the

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

⁵ The four MSRB-owned examinations are the: Municipal Advisor Representative Qualification Examination; Municipal Fund Securities Limited Principal Qualification Examination; Municipal Securities Representative Qualification Examination; and the Municipal Securities Principal Qualification Examination and are all developed, implemented and maintained by the MSRB. In 2015, the MSRB filed amendments to A-16 to institute a test development fee for the Series 50 examination and to change the test development fee for each of the MSRB-owned examinations from \$60 to \$150 to address the growing disproportion between the examination fees collected and the program costs. See Exchange Act Release No. 74561 (March 23, 2015), 80 FR 16485 (March 27, 2015) (File No. SR-MSRB-2015-01).

⁶ 15 U.S.C. 78o-4(b)(2)(A).

¹⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

Board.⁷ Section 15B(b)(2)(L)(iii) of the Act further requires the MSRB to establish professional standards for municipal advisors.⁸ A professional qualification examination is intended to determine whether an individual meets the MSRB's required qualification standards. On November 20, 2018, the SEC approved the MSRB's proposed rule change to, among other things, amend Rule G-3, on professional qualification requirements, to require persons who meet the definition of a municipal advisor principal⁹ to pass the Series 54 examination in order to become appropriately qualified as a municipal advisor principal.¹⁰ The Series 54 examination is designed to measure an individual's ability to apply the applicable federal securities laws and MSRB rules to the municipal advisory activities of the municipal advisor. The establishment of qualification requirements for municipal advisor principals ensures that such persons have a specified level of competency that is appropriate in the public interest and for the protection of investors, and municipal entities and obligated persons.

The Series 54 examination, as with all MSRB-owned professional qualification examinations, has been developed by the MSRB in consultation with the MSRB's Professional Qualification Advisory Committee (PQAC) and its retained psychometrician,¹¹ and in accordance with The Standards for Educational and Psychological Testing.¹² The MSRB adhered to recognized test development practices by performing a job study to determine the appropriate topics to be covered on the Series 54 examination and the weighting of such topics.¹³

The proposed test development fee to be assessed under Rule A-16 is intended to partially offset the overall program costs to the MSRB. As the MSRB has previously noted, the examination fee for each of its examinations has not previously been, and is not intended to fully offset the MSRB's program costs, but is intended to help defray a portion of the cost of developing and implementing the examinations, as well as the costs associated with monitoring the examinations for effectiveness and ongoing maintenance of the examinations through a review of the content and questions.¹⁴ The MSRB believes the test development fee of \$150 for the Series 54 examination is appropriate and consistent with the fee assessed for other MSRB-owned examinations.

Municipal advisors who enroll an associated person to take the Series 54 examination, as with all MSRB-owned examinations, will also pay an administration and delivery fee to the Financial Industry Regulatory Authority ("FINRA"), which provides the online portal for examination enrollment and coordinates with the testing vendor for the delivery of the MSRB's professional qualification examinations. The additional fee is assessed by FINRA at the time a municipal advisor enrolls an individual to take an examination.¹⁵

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(J) of the Act¹⁶ which provides that:

each municipal securities broker, municipal securities dealer, and municipal advisor shall pay to the Board such reasonable fees and charges as may be necessary or appropriate to defray the costs and expenses of operating and administering the Board. Such rules shall specify the amount of such fees and charges

The MSRB believes the proposed rule change appropriately aligns with the requirements under Section 15B(b)(2)(J) in that it provides for reasonable dues, fees and other charges for municipal advisors and seeks to partially offset program costs associated with staff's effort to develop and deliver such examinations and represents an

equitable allocation of fees for all MSRB-owned examinations.¹⁷

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Act¹⁸ requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purpose of the Act. The MSRB believes the proposed rule change is necessary and appropriate to ensure that municipal advisors contribute to defraying the expenses associated with the overall program costs for administering the MSRB's professional qualification examinations, which was established, as authorized by the Act, to prescribe "standards of training, experience, competence, and such other qualifications as the Board finds necessary" ¹⁹ As the MSRB has previously noted, revenue from the examination fee falls well-short of actual program costs.²⁰ Additionally, the proposed rule change would align with the existing test development fees, which are equitable to each dealer and municipal advisor without regard to the nature of that regulated entity's business and are assessed only as to those individuals associated with a regulated entity that are engaging in activities that require such individuals to become appropriately qualified.

In addition, Section 15B(b)(2)(L)(iv) of the Act²¹ provides that MSRB rules may "not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud." The MSRB believes that its professional qualification examinations, including the Series 54 examination, promote compliance with applicable laws and regulations and are necessary for the protection of investors, municipal entities and obligated persons. The MSRB does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of these provisions and their purposes under the Act. The fee for a professional qualification examination is a one-time fee for individuals who pass the examination and such fee is equitably applied across all municipal advisors. On net, the total examination fees to be

⁷ 15 U.S.C. 78o-4(b)(2)(A)(iii).

⁸ 15 U.S.C. 78o-4(b)(2)(L)(iii).

⁹ Under Rule G-3(e), a "municipal advisor principal" is defined as "a natural person associated with a municipal advisor who is qualified as a municipal advisor representative and is directly engaged in the management, direction or supervision of the municipal advisory activities of the municipal advisor and its associated persons."

¹⁰ See Exchange Act Release No. 84630 (November 20, 2018), 83 FR 60927 (November 27, 2018) (File No. SR-MSRB-2018-07).

¹¹ A psychometrician is an expert in a field of study devoted to testing, measurement, and assessment.

¹² See American Educational Research Association, American Psychological Association and National Council on Measurement in Education, "The Standards for Educational and Psychological Testing" (2d ed. 2014).

¹³ The MSRB conducted a job study of municipal advisor principals via a web-based survey. The job study was sent to over 500 municipal advisors with the MSRB receiving 212 responses to the job study. A job study is an assessment of the essential skills that are required to complete a particular function and is used as a basis for defining relevant or suitable content for exam questions.

¹⁴ See *supra* note 5.

¹⁵ The total cost to take the Series 54 examination, inclusive of FINRA's administration and test delivery fee would be \$265.00. This cost is comparable to the total fee charged to take FINRA-administered professional qualification examinations.

¹⁶ 15 U.S.C. 78o-4(b)(2)(J).

¹⁷ *Id.*

¹⁸ 15 U.S.C. 78o-4(b)(2)(C).

¹⁹ 15 U.S.C. 78o-4(b)(2)(A).

²⁰ See *supra* note 5.

²¹ 15 U.S.C. 78o-4(b)(2)(L)(iv).

assessed under Rule A-16 will correlate to the number of individuals associated with a municipal advisor that is required, pursuant to Rule G-3, to take the Series 54 examination, which likely would be less for smaller municipal advisors.

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 on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act²² and Rule 19b-4(f)(2)²³ 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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-MSRB-2019-02 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-MSRB-2019-02. 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 MSRB. 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-MSRB-2019-02 and should be submitted on or before March 14, 2019.

For the Commission, pursuant to delegated authority.²⁴

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02894 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85130; File No. SR-CboeEDGX-2019-004]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule as It Relates to Pricing for the Use of Certain Routing Strategies

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 1, 2019, Cboe EDGX Exchange, Inc. (the "Exchange" or "EDGX") 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 Exchange. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. ("EDGX" or the "Exchange") is filing with the Securities and Exchange Commission (the "Commission") a proposed rule change to amend the fee schedule applicable to the EDGX equities trading platform ("EDGX Equities") as it relates to pricing for the use of certain routing strategies. The text of the proposed rule change is attached as Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (http://markets.cboe.com/us/options/regulation/rule_filings/edgx/), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the EDGX Equities fee schedule to change the pricing applicable to orders routed using the ROUC routing strategy in connection with planned changes to the System routing table.³ ROUC is a routing strategy offered by the Exchange that is used to target certain low cost protected market centers by routing to those venues after accessing available liquidity on the EDGX Book and certain non-exchange destinations, and prior to routing to other trading centers included

³ The term "System routing table" refers to the proprietary process for determining the specific trading venues to which the System routes orders and the order in which it routes them. See Rule 11.13(b)(3). The Exchange reserves the right to route orders simultaneously or sequentially, maintain a different System routing table for different routing options and to modify the System routing table at any time without notice. *Id.*

²² 15 U.S.C. 78s(b)(3)(A)(ii).

²³ 17 CFR 240.19b-4(f)(2).

²⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

in the System routing table and posting to the EDGX Book, if possible. The Exchange periodically changes the low cost venues targeted by the ROUC routing strategy to ensure that the venues prioritized for routing can be accessed at a low cost. Currently, four exchanges are included in the System routing table as low cost protected market centers: Cboe BYX Exchange, Inc. (“BYX”), Cboe EDGA Exchange, Inc. (“EDGA”), Nasdaq BX, Inc. (“BX”), and New York Stock Exchange LLC (“NYSE”). Pursuant to Rule 11.11(g), the Exchange has determined to modify System routing table such that NYSE would no longer be listed as a low cost protected market center where orders are first routed after seeking available liquidity on the EDGX Book and certain non-exchange destinations. In addition, the Exchange has decided to add NYSE American LLC (“NYSE American”) and NYSE National, Inc. (“NYSE National”) as low cost protected market centers. These changes to the System routing table are scheduled to be introduced on February 1, 2019.

Currently, orders routed using the ROUC routing strategy are provided a rebate of \$0.00150 per share when routed to BYX,⁴ charged a fee of \$0.00290 per share when routed to Nasdaq PSX (“PSX”),⁵ or charged a fee of \$0.00200 per share when routed to a non-exchange destination.⁶ Orders routed to other markets may be subject to different non-ROUC specific pricing. The Exchange proposes to add two new fee codes, MX and NX, that relate to orders routed to NYSE American and NYSE National, respectively, using the ROUC routing strategy. In securities at or above \$1.00, orders routed using the ROUC routing strategy would be charged a fee of \$0.00020 per share if executed on NYSE American, and provided a rebate of \$0.00200 per share if executed on NYSE National. As proposed, the Exchange would not charge a fee or provide a rebate for orders routed in securities priced below \$1.00. The proposed fees and rebates chosen for routing to these venues generally reflect the current transaction

⁴ See EDGX Equities Schedule of Fees, fee code “BY.” This rebate applies to securities priced at or above \$1.00. For securities priced below \$1.00, a fee equal to 0.10% of the dollar value is applied instead. *Id.*

⁵ See EDGX Equities Schedule of Fees, fee code “K.” This fee applies to securities priced at or above \$1.00. For securities priced below \$1.00, a fee equal to 0.30% of the dollar value is applied instead. *Id.*

⁶ See EDGX Equities Schedule of Fees, fee code “Q.” This fee applies to securities priced at or above \$1.00. For securities priced below \$1.00, a fee equal to 0.30% of the dollar value is applied instead. *Id.*

fees and rebates available for accessing liquidity on those markets.⁷

In addition, pursuant to fee code “I,” orders routed to EDGA that are not otherwise eligible for routing strategy specific rates specified in the fee schedule are provided a rebate of \$0.00240. The Exchange proposes that this rebate, which is a pass through of the current rebate available on EDGA, be applied specifically to orders routed using its low cost routing strategies—*i.e.*, ROUC and ROUE. Orders routed to EDGA using other routing strategies would continue to qualify for routing strategy specific rates, which also largely reflect the current rebate available for orders that remove liquidity on EDGA,⁸ or in limited circumstances would be charged based on the Exchange’s default routing rate of \$0.00300 per share.⁹

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6 of the Act,¹⁰ in general, and furthers the requirements of Section 6(b)(4),¹¹ in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other persons using its facilities. The Exchange believes the proposed routing fee changes are appropriate as they reflect changes to the System routing table used to determine the order in which venues are accessed using the ROUC routing strategy. ROUC specifically targets certain equities exchanges that provide cheap executions or rebates to liquidity removing orders, and routes to those venues after trading with the EDGX Book and certain non-exchange destinations, and prior to accessing liquidity that may be available on other venues on the System routing table. The Exchange believes that the proposed changes reflect the intent of members when they submit routable order flow to

⁷ NYSE American currently charges a fee for removing liquidity that is \$0.00020 per share in securities priced at or above \$1.00, and 0.25% of the total dollar value of the transaction in securities priced below \$1.00. See NYSE American Equities Price List, I. Transaction Fees. NYSE National currently provides a rebate of \$0.00200 per share in securities priced at or above \$1.00 for members that achieve their taking tier. See NYSE National Schedule of Fees and Rebates, I. Transaction Fees, B. Tiered Rates. Orders that remove liquidity in securities below \$1.00 are executed without charge or rebate. See NYSE National, Schedule of Fees and Rebates, I. Transaction Fees, A. General Rates.

⁸ See *e.g.*, EDGX Equities Schedule of Fees, fee codes “AA” and “RR,” which similarly provide a rebate of \$0.00240 for orders routed to EDGA using the ALLB and DIRC routing strategies, respectively.

⁹ See EDGX Equities Schedule of Fees, fee code “X.”

¹⁰ 15 U.S.C. 78f.

¹¹ 15 U.S.C. 78f(b)(4).

the Exchange using the ROUC routing strategy.

The Exchange believes that it is reasonable and equitable to provide special pricing for orders routed to NYSE American and NYSE National using the ROUC routing strategy. As mentioned previously, the Exchange is adding these two exchanges to its list of low cost protected market centers, and wishes to provide the benefit of the rebate or lower fee provided by those markets to EDGX members using the ROUC routing strategy. The Exchange believes that these changes may increase interest in the Exchange’s ROUC routing strategy, in particular, by passing on better pricing to EDGX members that choose to enter such orders on the Exchange, thereby encouraging additional order flow to be entered to the EDGX Book.

The rebates provided to orders routed to NYSE National using the ROUC routing strategy would be limited to order price at or above \$1.00 in light of the fact that NYSE National does not provide rebates to liquidity removing orders in securities priced below \$1.00. For securities priced below \$1.00, the Exchange would charge no fee and provide no rebate, which is equivalent to pricing on NYSE National.¹² Without limiting the proposed rebate for NYSE National to securities priced at or above \$1.00, the Exchange would pay a significant rebate that would not be recouped via a rebate earned from the execution venue. The Exchange believes that is reasonable and equitable to limit routing rebates to circumstances where the Exchange would actually earn a rebate from the away venue in order to properly recoup the costs of accessing liquidity on such markets. Similarly, the Exchange would charge no fee and provide no rebate for orders routed to NYSE American using the ROUC routing strategy in securities priced below \$1.00. Although such orders are charged a fee by NYSE American equal to 0.25% of the total dollar value of the transaction, the Exchange has determined to provide free executions as an additional inducement for members to send their routable order flow to EDGA.

The Exchange also believes that it is reasonable and equitable to limit fee code I to orders routed to EDGA using the ROUC and ROUE routing strategies, which are both intended as low cost routing strategies. This fee code is a catchall for orders routed to EDGA and applies to a limited subset of routing strategies that are not otherwise subject to special pricing pursuant to other fee

¹² See supra note 8.

codes. The Exchange believes that specifying the routing strategies to which this fee code would be applied will increase transparency around the pricing for orders routed using Exchange provided routing strategies. With this change, only a limited number of routing strategies would be subject to a higher default routing fee. The Exchange believes that it is reasonable and equitable to limit its pass through rebates to specified routing strategies where the Exchange has determined to offer such pricing as an inducement for members to utilize such strategies. The Exchange's routing functionality is offered on a purely voluntary basis and members that utilize routing strategies that are not subject to such an incentive are free to route their orders directly to EDGA, or to use other routing strategies where the Exchange has determined to provide pass through rebates.

Finally, the Exchange believes that the proposed changes are equitable and not unfairly discriminatory as the proposed fees and rebates would apply equally to all members that use the Exchange to route orders using the associated routing strategy. The proposed fees are designed to reflect the fees charged and rebates offered by certain away trading centers that are accessed by Exchange routing strategies, and are being made in conjunction with changes to the System routing table designed to provide members with low cost executions for their routable order flow. Furthermore, if members do not favor the proposed pricing, they can send their routable orders directly to away markets instead of using routing functionality provided by the Exchange. Routing through the Exchange is voluntary, and the Exchange operates in a competitive environment where market participants can readily direct order flow to competing venues or providers of routing services if they deem fee levels to be excessive.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed routing fee changes are designed to reflect changes being made to the System routing table used to determine where to send certain routable orders, and generally provide better pricing to members for orders routed to low cost protected market centers using the Exchange's routing strategies. The Exchange operates in a highly competitive market in which market participants can readily direct

their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and paragraph (f) of Rule 19b-4¹⁴ 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 will institute proceedings 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:

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-CboeEDGX-2019-004 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-CboeEDGX-2019-004. 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 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-CboeEDGX-2019-004 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02890 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85141; File No. SR-CBOE-2019-008]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Cboe Order Routing Subsidy Program ("ORS") and Complex Order Routing Subsidy Program ("CORS") To Exclude Subsidy Payments for Contracts Executed as Qualified Contingent Cross ("QCC") Orders

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 17 CFR 240.19b-4(f).

¹⁵ 17 CFR 200.30-3(a)(12).

“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 1, 2019, Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) 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 Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the “Exchange” or “Cboe Options”) proposes to amend the Cboe Order Routing Subsidy Program (“ORS”) and Complex Order Routing Subsidy Program (“CORS”) to exclude subsidy payments for contracts executed as Qualified Contingent Cross (“QCC”) orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange’s website (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange’s Office of the Secretary, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its ORS and CORS Programs (collectively “Programs”) by eliminating the payment of subsidies for contracts executed as QCC orders. Currently, the ORS and CORS Programs allow the Exchange to enter into subsidy arrangements with any Cboe Trading Permit Holder (“TPH”) (each, a “Participating TPH”)

or Non-Cboe TPH broker-dealer (each a “Participating Non-Cboe TPH”) that meet certain criteria and provide certain order routing functionalities to other TPHs, Non-Cboe TPHs and/or use such functionalities themselves.³ Participating TPHs or Participating Non-Cboe TPHs in the ORS and CORS Programs (the “Participants”) receive a payment from the Exchange for every executed contract routed to the Exchange through their system in all classes excluding classes in Underlying Symbols List A, Sector Indexes, DJX, MXEA, MXEF, XSP and XSPAM. Additionally, Participants do not receive payment for contracts executed in the Automated Improvement Mechanism (“AIM”),⁴ as contracts that execute via AIM already have an opportunity to earn various rebates and discounts. Similarly, contracts executed as QCC orders also have other opportunities to earn various rebates and discounts.⁵ Therefore, the Exchange proposes to expressly exclude contracts executed as QCC orders from the ORS and CORS Programs’ payment of subsidies.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.⁶ Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁷ requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to

and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)⁸ requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange believes the proposed change to the ORS and CORS Programs to expressly exclude contracts executed as QCC orders from the Programs’ payment of subsidies is reasonable as Participants will merely no longer receive a subsidy for QCC orders. The Exchange notes that AIM orders also are not eligible to receive a subsidy under the Programs. The Exchange believes it is equitable and not unfairly discriminatory to exclude QCC trades from both Programs because, like AIM orders, orders executed as a QCC already have an opportunity to earn various rebates or discounts.⁹ Lastly, the Exchange believes that the proposed change is equitable and not unfairly discriminatory because the change is applicable to all Participants and any Cboe TPH or broker-dealer that is not a Cboe TPH may continue to avail itself of the arrangements under the Programs, provided that their routing functionality incorporates the respective requirements of each Program.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change will impose an unnecessary burden on intramarket competition because it will apply equally to all Participants in the Programs. Although the subsidy for orders routed to the Exchange through a Participant’s system only applies to Participants of the Programs, the subsidies are designed to encourage the sending of more orders to the Exchange, which should provide greater liquidity and trading opportunities for all market participants. Further, the Exchange does not believe that such change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange notes that excluding an order type from eligibility for a subsidy under the Cboe Fee Schedule does not pose any

³ See Cboe Fees Schedule, “Order Router Subsidy Program” and “Complex Order Router Subsidy Program” tables for more details on the ORS and CORS Programs.

⁴ See Securities and Exchange Act Release 34-73354 (October 15, 2015) 79 FR 62988 (October 21, 2014) (SR-CBOE-2014-075) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the CBOE Order Routing Subsidy Program and the Complex Order Routing Subsidy Program).

⁵ See e.g., Cboe Fees Schedule, “QCC Rate Table”, which provides a \$0.10 per contract credit to the initiating side of a non-customer QCC transaction and “ETF and ETN Options Rate Table” Footnote 8, which provides that the Exchange will waive the transaction fee for public customer orders in all ETF and ETN options that are executed, among other order types, as a QCC.

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ *Id.*

⁹ See *supra* note 5.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

competitive advantages over other exchanges. Further, the proposed changes only affect trading on the Exchange. To the extent that the proposed changes make Cboe Options a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become Cboe Options market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁰ and paragraph (f) of Rule 19b-4¹¹ 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 will institute proceedings 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:

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-CBOE-2019-008 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-CBOE-2019-008. 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-CBOE-2019-008 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹²

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02902 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85144; File No. SR-NYSENAT-2019-02]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31 Relating to the Minimum Trade Size Modifier

February 14, 2019.

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 February 6, 2019, NYSE National, Inc. (the

"Exchange" or "NYSE National") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.31 relating to the Minimum Trade Size Modifier. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 relating to the Minimum Trade Size ("MTS") Modifier. Specifically, the Exchange proposes to make the MTS Modifier available for Non-Displayed Limit Orders.⁴ The Exchange also proposes to provide additional optionality for ETP Holders using the MTS Modifier with Limit IOC Orders, Non-Displayed Limit Orders, Midpoint Liquidity ("MPL") Orders, and Tracking Orders. As proposed, ETP Holders could choose how such orders would trade on arrival to trade either with (i) orders that in the aggregate meet the MTS (current functionality), or (ii) individual orders that each meet the MTS (proposed functionality).

⁴ See Rule 7.31(d)(2). In sum, A Non-Displayed Limit Order is a Limit Order that is not displayed and does not route. *Id.*

¹² 17 CFR 200.30-3(a)(12).

¹⁵ U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f).

The MTS Modifier is currently available for Limit IOC Orders,⁵ MPL Orders,⁶ and Tracking Orders.⁷ As such, the MTS Modifier is currently available only for orders that are not displayed and do not route. On arrival, both Limit IOC Orders and MPL Orders with an MTS Modifier will trade against contra-side orders in the Exchange Book that in the aggregate, meet the MTS.⁸ Once resting, MPL Orders and Tracking Orders with an MTS Modifier function similarly: If a contra-side order does not meet the MTS, the incoming order will not trade with and may trade through the resting order with the MTS Modifier. In addition, both MPL Orders and Tracking Orders with an MTS Modifier will be cancelled if such orders are traded in part or reduced in size and the remaining quantity is less than the MTS.

The Exchange proposes to amend its rules to make MTS Modifier functionality available for an additional non-displayed order that does not route, *i.e.*, Non-Displayed Limit Orders. The Exchange also proposes to add an option that an order with an MTS Modifier would trade on entry only with individual orders that each meet the MTS. This proposed change is based on the rules of its affiliate, NYSE American LLC (“NYSE American”), which offers the option for orders with an MTS to trade on entry only with individual orders that each meet the MTS of the incoming order.⁹ Both of these proposed changes are also based on the rules of the Nasdaq Stock Market LLC (“Nasdaq”) and Investors Exchange LLC

(“IEX”), which both offer minimum trade size functionality for orders that are not displayed and that do not route.¹⁰ Nasdaq and IEX, as well as Cboe BYX Exchange, Inc. (“BYX”), Cboe BZX Exchange, Inc. (“BZX”), Cboe EDGA Exchange, Inc. (“EDGA”), and Cboe EDGX Exchange, Inc. (“EDGX”, together with BYX, BZX, and EDGA, the “Cboe Equity Exchanges”), also all offer the option for orders with a minimum trade size to trade on entry only with individual orders that each meet the minimum trade size condition of the incoming order.¹¹

Rule 7.31(i)(3) currently states that on arrival, an order to buy (sell) with an MTS Modifier will trade with sell (buy) orders in the Exchange Book that in the aggregate meet such order’s MTS. As amended, Rule 7.31(i)(3)(B) would now require an ETP Holder to specify one of the following instructions with respect to how an order with an MTS Modifier would trade on arrival (new text underlined):

(i) An order to buy (sell) with an MTS Modifier will trade with sell (buy) orders in the Exchange Book that in the aggregate meet such order’s MTS[.]; or

(ii) An order to buy (sell) with an MTS Modifier will trade with individual sell (buy) order(s) in the Exchange Book that each meets such order’s MTS.

Proposed paragraph (i)(3)(B)(ii) is new and reflects the Exchange’s proposal to add an alternative to how an order with an MTS Modifier would trade on arrival. An order with an MTS Modifier that is to trade upon entry only with individual orders that each meet the MTS would execute against resting orders in accordance with Rule 7.36, Order Ranking and Display, until it

¹⁰ See Nasdaq Rule 4703(e) (Nasdaq’s “Minimum Quantity Order” may not be displayed and will be rejected if it includes an instruction to route) and IEX Rule 11.190(b)(11)(A) (IEX’s “Minimum Quantity Order” or “MQTY” is a non-displayed, non-routable order”).

¹¹ See Nasdaq Rule 4703(e) (Nasdaq’s “Minimum Quantity” order attribute allows for a Nasdaq participant to specify one of two alternatives to how a Minimum Quantity Order would be processed at the time of entry, one of which is that “the minimum quantity condition must be satisfied by execution against one or more orders, each of which must have a size that satisfies the minimum quantity condition”) and IEX Rule 11.190(b)(11)(G)(iii)(B) (On arrival, IEX’s “Minimum Execution Size with All-or-None Remaining” qualifier for IEX’s MQTY executes against each willing resting order in priority, provided that each individual execution size meets its effective minimum quantity.) See also BYX Rule 11.9(c)(5); BZX Rule 11.9(c)(5); EDGA Rule 11.6(h); and EDGX Rule 11.6(h) (The Cboe Equity Exchanges each allow a User to alternatively specify the order not execute against multiple aggregated orders simultaneously and that the minimum quantity condition be satisfied by each individual order resting on the book).

reaches an order that does not satisfy the MTS, at which point it would be posted or cancelled in accordance with the terms of the order. This proposed rule text is also based on NYSE American Rule 7.31E(i)(3)(B).¹² Proposed Exchange Rule 7.31(i)(3)(B)(i) would describe the existing functionality as one of the instructions that would be available to ETP Holders.

As discussed above, the addition of this instruction for how orders with an MTS Modifier would trade on entry is based on the rules of NYSE American, Nasdaq, IEX, and the Cboe Equity Exchanges.¹³

* * * * *

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date of this proposed rule change by Trader Update. The Exchange anticipates that the implementation date will be in the second quarter of 2019.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the “Act”),¹⁴ in general, and furthers the objectives of Section 6(b)(5),¹⁵ in particular, because 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.

The Exchange believes that the proposal to expand the availability of the Exchange’s existing MTS Modifier to an additional non-displayed, non-routable order, *e.g.*, Non-Displayed Limit Orders, would 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, because the proposed rule change is based on similar minimum trade size functionality on Nasdaq and IEX, which both similarly make minimum trade size functionality available to non-displayed, non-routable orders.¹⁶

The Exchange also believes that the proposal would remove impediments to,

¹² See *supra* note 9.

¹³ See *supra* notes 9 and 11.

¹⁴ 15 U.S.C. 78f(b).

¹⁵ 15 U.S.C. 78f(b)(5).

¹⁶ See *supra* note 10.

⁵ See Rule 7.31(b)(2)(A). In sum, a Limit Order designated IOC is to be traded in whole or in part on the Exchange as soon as such order is received, and the quantity not so traded is cancelled. *Id.*

⁶ See Rule 7.31(d)(3). In sum, an MPL Order is a “Limit Order that is not displayed and does not route, with a working price at the midpoint of the PBBO.” *Id.*

⁷ See Rule 7.31(d)(4). In sum, a Tracking Order is an order to buy (sell) with a limit price that is not displayed, does not route, must be entered in round lots and designated Day, and will trade only with an order to sell (buy) that is eligible to route.

⁸ Tracking Orders, including Tracking Orders with an MTS Modifier, are passive orders that do not trade on arrival.

⁹ See NYSE American Rule 7.31E(i)(3)(B). See also Securities Exchange Act Release No. 81672 (September 21, 2017), 82 FR 45099 (September 27, 2017) (SR-NYSEAMER-2017-17) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 7.31E Relating to the Minimum Trade Size Modifier for Additional Order Types and Expanding the Minimum Trade Size Modifier for Existing Order Types). The Exchange understands that NYSE American as well as its other affiliated exchanges, the New York Stock Exchange, Inc. (“NYSE”), and NYSE Arca, Inc. (“NYSE Arca”, together with the Exchange and NYSE, the “Affiliate SROs”) intend to file similar proposed rule changes with the Commission to extend the availability of their respective MTS Modifiers to Non-Displayed Limit Orders.

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 because it would provide ETP Holders with the option for orders with a MTS Modifier to trade on entry only with individual orders that each meets the MTS of the incoming order, thereby providing ETP Holders with more control in how such orders could execute. The proposed rule change is based on similar options available for users of minimum trade size functionality on the Exchange's affiliate, NYSE American, as well as Nasdaq, IEX, and the Cboe Equity Exchanges.¹⁷ The Exchange further believes that this proposed option would remove impediments to, and perfect the mechanism of, a free and open market and a national market system because it would allow ETP Holders to provide an instruction that an order with an MTS Modifier would not trade with orders that are smaller in size than the MTS for such order, thereby providing ETP Holders with more control over when an order with an MTS Modifier may be executed.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change is designed to increase competition by making available on the Exchange functionality that is already available on Nasdaq, IEX, and the Cboe Equity Exchanges. The Exchange also believes that the proposed rule change would promote competition by providing market participants with an additional venue to which to route non-displayed, non-routable orders with an MTS Modifier.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act¹⁸ and Rule 19b-4(f)(6) thereunder.¹⁹

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 to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NYSENAT-2019-02 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-NYSENAT-2019-02. 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

¹⁸ 15 U.S.C. 78s(b)(3)(A).

¹⁹ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. 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-NYSENAT-2019-02, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁰

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019-02898 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85139; File No. SR-BOX-2019-02]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC ("BOX") Facility To Modify Certain Agency Order Fees for Facilitation and Solicitation Transactions

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 1, 2019, BOX Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon filing with the Commission. The

²⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

¹⁷ See *supra* notes 9 and 11.

Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the Fee Schedule to amend the Fee Schedule [sic] on the BOX Options Market LLC ("BOX") options facility. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's internet website at <http://boxexchange.com>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to amend Section I.C (Facilitation and Solicitation Transactions).⁵ Specifically, the Exchange proposes to decrease the Agency Order⁶ fees for Professional Customers, Broker Dealers and Market Makers from \$0.15 to \$0.00 for Penny Pilot and Non-Penny Pilot Classes.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and

other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed changes are reasonable as the Exchange is eliminating the fees for Professional Customers, Broker Dealers and Market Makers for their Agency Orders in the Facilitation and Solicitation mechanism.⁸ The Exchange believes that eliminating these fees will attract order flow to these mechanisms which will result in greater liquidity and ultimately benefit all Participants trading on the Exchange. Further, the Exchange believes that the proposed change is equitable and not unfairly discriminatory, as the proposed change applies to all Professional Customers, Broker Dealers and Market Makers. The Exchange notes that there is no fee charged to Public Customers for their Agency Orders in the Facilitation and Solicitation mechanism.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing exchanges. In such an environment, the Exchange must continually review, and consider adjusting, its fees to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes to the Facilitation and Solicitation Transaction fees will not impose a burden on competition among various Exchange Participants. Rather, BOX believes that the changes will result in the Participants being charged appropriately for these transactions and are designed to enhance competition in the Facilitation and Solicitation mechanisms. Submitting an order is entirely voluntary and Participants can determine which order type they wish to submit, if any, to the Exchange. Further, the Exchange believes that this proposal will enhance competition between exchanges because it is designed to allow the Exchange to better compete with other exchanges for order flow. The Exchange does not believe that the proposed change will burden

competition by creating a disparity between the fees an initiator pays and the fees a competitive responder pays that would result in certain Participants being unable to compete with initiators. In fact, the Exchange believes that these changes will not impair these Participants from adding liquidity and competing in the Facilitation and Solicitation mechanisms, and will help promote competition by providing incentives for market participants to submit Agency Orders, and thus benefit all Participants trading on the Exchange by attracting customer order flow.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act⁹ and Rule 19b-4(f)(2) thereunder,¹⁰ because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BOX-2019-02 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.

⁵ Transactions executed through the Solicitation Auction mechanism and Facilitation Auction mechanism.

⁶ An Agency Order is a block-size order that an Order Flow Provider seeks to facilitate as agent through the Facilitation Auction or Solicitation Auction mechanism.

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ The Exchange notes that it previously did not charge Broker Dealers, Professional Customers and Market Makers for Agency Orders in the Facilitation and Solicitation mechanism. See SR-BOX-2015-29.

⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁰ 17 CFR 240.19b-4(f)(2).

All submissions should refer to File Number SR–BOX–2019–02. 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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. 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–BOX–2019–02, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019–02900 Filed 2–20–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85137; File No. SR–FICC–2018–013]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Designation of Longer Period for Commission Action and Reopening the Period for Comment on Proposed Rule Change To Expand Sponsoring Member Eligibility in the Government Securities Division Rulebook and Make Other Changes

February 14, 2019.

On December 13, 2018, 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”) ¹ and Rule 19b–4 thereunder,² proposed rule change SR–FICC–2018–013 to expand sponsoring member eligibility and make other changes.³ The proposed rule change was published for comment in the **Federal Register** on December 31, 2018.⁴ As of February 13, 2019, the Commission has received five comment letters to the proposed rule change,⁵ including a response letter from FICC.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ On December 13, 2018, FICC also filed the proposal contained in the proposed rule change as advance notice SR–FICC–2018–802 with the Commission pursuant to Section 806(e)(1) of the Dodd-Frank Wall Street Reform and Consumer Protection Act entitled the Payment, Clearing, and Settlement Supervision Act of 2010 (“Clearing Supervision Act”), 12 U.S.C. 5465(e)(1), and Rule 19b–4(n)(1)(i) of the Act, 17 CFR 240.19b–4(n)(1)(i).

⁴ Securities Exchange Act Release No. 84951 (December 21, 2018), 83 FR 67801 (December 31, 2018) (SR–FICC–2018–013) (“Notice”).

⁵ See letter from Robert E. Pooler, Jr., Chief Financial Officer, Ronin Capital, LLC, dated January 18, 2019, to Brent J. Fields, Secretary, Commission (“Ronin Letter”); letter from James Tabacchi, Chairman, Independent Dealer and Trade Association, dated January 22, 2019, to Brent J. Fields, Secretary, Commission (“IDTA Letter”); letter from Robert Toomey, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, dated January 22, 2019, to Brent J. Fields, Secretary, Commission (“SIFMA Letter”); letter from Stephen John Berger, Managing Director, Government & Regulatory Policy, Citadel, dated January 30, 2019, to Brent J. Fields, Secretary, Commission (“Citadel Letter”); and letter from Murray Pozmanter, Managing Director, DTCC, dated February 4, 2019, to Brent J. Fields, Secretary, Commission (“FICC Response Letter”). See comments on the proposed rule change (SR–FICC–2018–013), available at <https://www.sec.gov/comments/sr-ficc-2018-013/srficc2018013.htm>. Because the proposal contained in the proposed rule change was also filed as an advance notice, *supra* note 3, the Commission is considering all public comments received on the proposal regardless of whether the comments were submitted to the advance notice or the proposed rule change.

Section 19(b)(2) of the Act⁶ provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for the proposed rule change is February 14, 2019.

The Commission is extending the 45-day time period for Commission action on the proposed rule change. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider and take action on the proposed rule change.

Accordingly, pursuant to Section 19(b)(2) of the Act⁷ and for the reasons stated above, the Commission designates March 31, 2019 as the date by which the Commission shall either approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–FICC–2018–013).

The Commission also seeks additional comment to help further inform its analysis of the proposed rule change. The comment period for the proposed rule change ended on January 22, 2019.⁸ As of February 13, 2019, the Commission has received five comment letters to the proposed rule change.⁹ The Commission is reopening the comment period for the proposed rule change to allow interested persons additional time to analyze the issues and prepare their comments. Accordingly, the Commission designates [insert date 21 days from publication in the **Federal Register**] as the date comments should be submitted on or before.

Specifically, the Commission invites interested persons to provide views, data, and arguments concerning the proposed rule change, including whether the proposed rule change is consistent with the Act and the applicable rules or regulations thereunder. Please note that comments previously received on the substance of the proposed rule change will be considered together with comments

⁶ 15 U.S.C. 78s(b)(2).

⁷ 15 U.S.C. 78s(b)(2).

⁸ Notice, 83 FR at 67808.

⁹ See *supra* note 5.

¹¹ 17 CFR 200.30–3(a)(12).

submitted in response to this notice. Therefore, while commenters are free to submit additional comments at this time, they need not re-submit earlier comments.

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-2018-013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-FICC-2018-013. 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-rule-filings.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-2018-013 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02896 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85138; File No. SR-MIAX-2019-02]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors

February 14, 2019.

Pursuant to the provisions of Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 6, 2019, Miami International Securities Exchange, LLC ("MIAX Options" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors.

The text of the proposed rule change is available on the Exchange's website at <http://www.miaxoptions.com/rule-filings/> at MIAX Options' principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the

places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On October 12, 2018, the Securities and Exchange Commission ("SEC") approved a proposal by the MIAX Exchange (the "Exchange") to list and trade on the Exchange, options on the SPIKES™ Index, a new index that measures expected 30-day volatility of the SPDR S&P 500 ETF Trust.³ To establish the settlement value for the Index, a final settlement price calculation will occur once per month, on the morning of SPIKES Index options expiration.⁴

The Exchange proposes to amend Exchange Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, to adopt a provision specifically related to its volatility index product. Currently, subparagraph (b)(1), Transactions at the Open, of Rule 521, provides that for a transaction occurring as part of the Opening Process⁵ (as described in Rule 503) the Exchange will determine the Theoretical Price⁶ if there is no NBB (National Best Bid) or NBO (National Best Offer) for the affected series just prior to the erroneous transaction or if the bid/ask differential of the NBB and NBO just prior to the erroneous transaction is equal to or greater than the Minimum Amount set forth in the chart contained in sub-paragraph (b)(3) of this rule.⁷ If the bid/ask differential is less than the Minimum Amount, the Theoretical Price is the NBB or NBO just prior to the erroneous transaction. The Exchange now proposes to adopt new subparagraph (A) to state that for transactions occurring in any option series being used to calculate the final settlement price of a volatility index on the final settlement day, the Theoretical

³ See Securities Exchange Act Release No. 84417 (October 12, 2018), 83 FR 52865 (October 18, 2018) (SR-MIAX-2018-14) (Order Granting Approval of a Proposed Rule Change to List and Trade Options on the SPIKES™ Index).

⁴ See Exchange Rule 503.02.

⁵ See Exchange Rule 503(f).

⁶ See Exchange Rule 521(b).

⁷ If the bid price at the time of the trade was below \$2.00 the Minimum Amount is \$0.75, similarly if the bid price at the time of the trade is between \$2.00 and \$5.00, the Minimum Amount is \$1.25; above \$5.00 to \$10.00, \$1.50; above \$10.00 to \$20.00, \$2.50; above \$20.00 to \$50.00, \$3.00; above \$50.00 to \$100.00, \$4.50; above \$100, \$6.00. See Exchange Rule 521(b)(3).

¹⁰ 17 CFR 200.30-3(a)(31).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Price is the first quote after the transaction(s) in question that does not reflect the erroneous transaction(s), provided that the quote size is for at least the overall size of the opening trade, if the quote size is for less than the overall size of the opening trade, then paragraph (c) and (d) shall not apply.

For erroneous sell transactions, the size of the bid would be used and for erroneous buy transactions, the size of the offer would be used. For example, if the opening trade in Series XYZ is for a total of 200 contracts and the bid or offer, as applicable, of the first quote after the transaction(s) in question that does not reflect the erroneous transaction(s) is for 500 contracts, the transaction in question would qualify for treatment under the Exchange's obvious error rule. If the bid or offer, as applicable, of the quote is for only 100 contracts, then the transaction in question would not be subject to consideration under the Exchange's obvious error rule. Upon the completion of the final settlement price calculation the proposed provision would no longer be applicable and all provisions of Rule 521 would again be in force.

By establishing a size threshold for certain transactions occurring during the Exchange's Opening Process, the proposal ensures that there is sufficient liquidity in a series for which a valid Theoretical Price can be established for use in determining whether a transaction meets the conditions necessary to qualify as an Obvious⁸ or Catastrophic Error.⁹ Further, due to the importance and finality of the final settlement price for expiring SPIKES Index Options, establishing a threshold based upon transaction size for obvious and catastrophic error consideration, and only for those options being used in the final settlement price calculation, ensures the timely completion of the settlement price calculation and protects the integrity of the calculation process from being unduly impacted by relatively small transactions.

Using the size of a transaction as the threshold for determining whether the transaction in question warrants consideration for obvious or catastrophic error review under the rule is a widely accepted standard and long standing practice in the industry.¹⁰ The Exchange notes that its proposed provision is substantially similar in all

material respects to a provision found in the Cboe Exchange's rule pertaining to the treatment of transactions in option series being used to calculate the final settlement price of a volatility index on the final settlement day.¹¹ Further, the Exchange notes that the industry has undertaken an effort to harmonize obvious error handling across all option exchanges and the Exchange's proposal aligns to currently accepted practices.¹²

2. Statutory Basis

The Exchange believes that its proposed rule change is consistent with Section 6(b) of the Act¹³ in general, and furthers the objectives of Section 6(b)(5) of the Act¹⁴ 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system and, in general, protects investors and the public interest by ensuring that there is sufficient liquidity in the market by which to derive a Theoretical Price for options being used in the final index settlement value calculation. Additionally, the proposed rule promotes just and equitable principles of trade and removes impediments to and perfects the mechanisms of a free and open market and a national market system and, in general, protects investors and the public interest by ensuring that the SPIKES index settlement value calculation is completed on a timely basis without unnecessary interruption.

Additionally, the proposed rule promotes cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, by

harmonizing the Exchange's obvious error rule with that of another exchange that has a similar process for determining the settlement price of an index.¹⁵

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

The Exchange does not believe the proposed rule change will impose any burden on inter-market competition as the proposed rule change is not a competitive filing and is designed to harmonize the Exchange's obvious error rule with that of the Cboe Exchange, which similarly offers a volatility index product that requires the calculation of a final settlement price.

Additionally, the Exchange does not believe the proposed rule change will impose any burden on intra-market competition as the rules of the Exchange apply equally to all Members¹⁶ of the Exchange.

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁷ and Rule 19b-4(f)(6) thereunder.¹⁸

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the

¹⁵ See *supra* note 10.

¹⁶ The term "Member" means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed "members" under the Exchange Act. See Exchange Rule 100.

¹⁷ 15 U.S.C. 78s(b)(3)(A).

¹⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

¹¹ See Cboe Exchange Rule 6.25(b)(1)(a).

¹² See Securities Exchange Act Release Nos. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR-MIAX-2015-35); 74911 (May 8, 2015), 80 FR 27717 (May 14, 2015) (SR-BOX-2015-18); 74898 (May 7, 2015), 80 FR 27354 (May 13, 2015) (SR-CBOE-2015-039); 74919 (May 8, 2015), 80 FR 27766 (May 15, 2015) (SR-PHLX-2015-43).

¹³ 15 U.S.C. 78f(b).

¹⁴ 15 U.S.C. 78f(b)(5).

⁸ See Exchange Rule 521(c).

⁹ See Exchange Rule 521(d).

¹⁰ See Securities Exchange Act Release No. 59981 (May 27, 2009), 74 FR 26447 (June 2, 2009) (SR-CBOE-2009-024) (Order Granting Approval of a Proposed Rule Change Related to Its Obvious Error Rules).

Act¹⁹ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)²⁰ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it would ensure that the Exchange will have a provision immediately available for handling obvious errors in option series being used to calculate the final settlement price of a volatility index on the final settlement day. For this reason, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal as operative upon filing.²¹

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 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:

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-MIAX-2019-02 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-MIAX-2019-02. 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-MIAX-2019-02 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²²

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019-02897 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85136; File No. SR-Phlx-2018-72]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Order Approving a Proposed Rule Change To Establish Rules Governing the Give Up of a Clearing Member by a Member Organization on Exchange Transactions

February 14, 2019.

I. Introduction

On November 6, 2018, Nasdaq PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² a proposed rule change to establish rules governing the "give up" process by which an Exchange member organization, in connection with executing a trade on the Exchange, indicates to the Exchange (*i.e.*, "gives up") the name of a Clearing Member³ that will be responsible for the clearance of that transaction. The proposed rule change was published for comment in the **Federal Register** on November 26, 2018.⁴ On January 9, 2019, pursuant to Section 19(b)(2) of the Act,⁵ the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.⁶ The Commission received three comment letters on the proposed rule change, each in support of the proposal.⁷ This order approves the proposed rule change.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Phlx Rule 1000(b)(3) (defining "Clearing Member" as a member organization that has been admitted to membership in the Options Clearing Corporation ("OCC") pursuant to the provisions of the rules of the Options Clearing Corporation).

⁴ See Securities Exchange Act Release No. 84624 (Nov. 19, 2018), 83 FR 60547 ("Notice").

⁵ 15 U.S.C. 78s(b)(2).

⁶ See Securities Exchange Act Release No. 84981, 83 FR 837 (Jan. 31, 2019) (designating February 24, 2019 as the date by which the Commission shall approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change).

⁷ See Letters to Brent J. Fields, Secretary, Commission, from: (1) Matthew R. Scott, President, Merrill Lynch Professional Clearing Corp, dated December 7, 2018 ("Scott Letter"); (2) Ellen Greene, Managing Director, SIFMA, dated December 17, 2018 ("SIFMA Letter"); and (3) John P. Davidson, President and Chief Operating Officer, OCC, dated December 19, 2018 ("Davidson Letter"). The comment letters are available at <https://www.sec.gov/comments/sr-phlx-2018-72/srphlx201872.htm>.

¹⁹ 17 CFR 240.19b-4(f)(6).

²⁰ 17 CFR 240.19b-4(f)(6)(iii).

²¹ For purposes only of waiving the 30-day operative delay, the Commission also has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²² 17 CFR 200.30-3(a)(12).

II. Description of the Proposed Rule Change

Exchange rules currently require that, in order to enter transactions on the Exchange, a member organization either must be a Clearing Member or have a Clearing Member agree to accept financial responsibility for the member organization's transactions via a clearing arrangement.⁸ Further, Phlx Rule 1052 provides generally that Clearing Members are responsible for the clearing their own Exchange transactions as well as Exchange transactions of each member organization that gives up the Clearing Member's name provided that the Clearing Member has authorized such member organization to give up its name on Exchange transactions. Exchange rules do not, however, establish a framework for the give up authorization process. To address this, Phlx proposes to adopt Rule 1037 and amend Rule 1052 to establish requirements for the give up process, including specific procedures, in greater detail.

Specifically, proposed Rule 1037 will allow Clearing Members to "opt in" and request that the Exchange systematically restrict use of one or more of its OCC clearing numbers (each a "Restricted OCC Number"). Once restricted, Exchange member organizations will not be able to give up the Restricted OCC Number to clear an Exchange transaction unless the Clearing Member previously has submitted to the Exchange written authorization permitting that member organization to give up that Restricted OCC Number. If a Clearing Member does not "opt in" to this process for a particular OCC number (a "Non-Restricted OCC Number"), that number would be available to be given up by any Exchange member organization.

Give Up Process for Restricted OCC Numbers

A Clearing Member that requests the Exchange to restrict use of one or more of its OCC clearing numbers would "opt in" by sending to the Exchange a completed "Clearing Member Restriction Form"⁹ that identifies the requested Restricted OCC Numbers.¹⁰

At the same time, the Clearing Member would list on the form the Exchange member organizations that it authorizes to give up that Restricted OCC Number (each an "Authorized Member Organization").¹¹ For newly Restricted OCC Numbers, the Exchange will require 90 days before the restriction becomes effective within the Exchange's system.¹²

Thereafter, a member organization may only give up a Restricted OCC Number if the member organization has previously been identified and processed by the Exchange as an Authorized Member Organization, except that a member organization may give up the Restricted OCC Number of its guarantor with whom it has a letter of guarantee without being identified as an Authorized Member Organization.¹³

Once a Restricted OCC Number is effective, a Clearing Member will be able to submit a new Clearing Member Restriction Form to authorize, or remove from authorization, a member organization from its list of Authorized Member Organizations approved to give up its Restricted OCC Number(s), as well as amend its list of Restricted OCC Numbers.¹⁴ The Exchange will promptly notify member organizations if they are no longer authorized to give up a Clearing Member's Restricted OCC Number.¹⁵

The Exchange will ensure the authorized use of Restricted OCC Numbers through its systems and will not allow an unauthorized member organization to give up a Restricted OCC Number. Specifically, for orders that are executed on the trading floor in open outcry using the Options Floor Based Management System ("FBMS"), the Exchange will reject the clearing portion of the trade if an unauthorized member organization enters a Restricted OCC Number.¹⁶ The member organization will receive notification of the rejected clearing information, and will be required to modify the clearing information by contacting the Exchange.¹⁷ For all other orders (*i.e.*,

proposes to amend Rule 1052 regarding financial responsibility of Exchange options transactions cleared through Clearing Members to clarify that Rule 1052 applies to all Clearing Members regardless of whether they "opt in" pursuant to Phlx Rule 1037.

¹¹ See *id.*

¹² See *id.*

¹³ See Proposed Phlx Rule 1037(d).

¹⁴ See Proposed Phlx Rule 1037(b)(iii). Such changes will be effective on the next business day under regular circumstances, but could be effective intra-day in unusual circumstances. See *id.*

¹⁵ See *id.*

¹⁶ See Proposed Phlx Rule 1037(c).

¹⁷ See *id.* According to the Exchange, the FBMS order will be executed, provided the terms of the

orders that are submitted directly to the exchange's system), the Exchange will not allow an unauthorized member organization to give up a Restricted OCC Number at the firm mnemonic level at the point of order entry.¹⁸

Misuse of the Rule

Finally, Phlx Rule 1037(e) provides that an intentional misuse of the Rule by any party is impermissible and may be treated as a violation of Rule 707 ("Conduct Inconsistent with Just and Equitable Principles of Trade") or Rule 708 ("Acts Detrimental to the Interest or Welfare of the Exchange").¹⁹

III. Discussion and Commission Findings

After careful consideration of the proposal, the Commission finds that the Exchange's proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.²⁰ In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act,²¹ which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

trade comply with the relevant Exchange rules, and the execution reported to the consolidated tape. The System will, however, reject the clearing portion, and the member organization will have to amend the clearing information by contacting the Exchange. See Notice, *supra* note 4 at n. 11.

¹⁸ See Proposed Phlx Rule 1037(c). Specifically, the Exchange states that its system will block the entry of the order from the outset. See Notice, *supra* note 4 at n. 13. The Exchange notes that a valid mnemonic will be required for any order to be submitted directly to the system, and a mnemonic will only be set up for a member organization if there is already a clearing arrangement in place for that firm either through a letter of guarantee (as is the case today) or as proposed in the case of a Restricted OCC Number, the member organization must be an Authorized Member Organization for that Restricted OCC Number. See *id.* As proposed, the system also will now restrict any post-trade allocation changes if the member organization is not authorized to use a Restricted OCC Number. See *id.*

¹⁹ See Proposed Phlx Rule 1037(e). See also Notice, *supra* note 4 at 60549 (providing one example of intentional misuse where a member organization sends orders to a Restricted OCC Number without authorization to do so).

²⁰ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²¹ 15 U.S.C. 78f(b)(5).

⁸ See Phlx Rule 1046 (Clearing Arrangements).

⁹ The Exchange represented in its filing that it will maintain this form and a list of the Restricted OCC Numbers on its website, which it will update on a regular basis, along with the Clearing Member's contact information to assist member organizations with requesting authorization for a Restricted OCC Number. See Notice, *supra* note 4 at n. 7.

¹⁰ See Proposed Phlx Rule 1037(b)(i). The restriction would remain in effect until terminated by the Clearing Member. See *id.* The Exchange also

The Commission received three comment letters on the proposed rule change, each supporting it.²² One commenter argues that the proposal “is a critical first step to reduce risk in listed-options clearing,” and will facilitate the ability of Clearing Members “to properly assess and enforce credit limits for authorized executing brokers and their clients.”²³ Another commenter notes that the Exchange’s proposal is the culmination of efforts among industry participants to address and ultimately reduce clearing member risks.²⁴ Further, one commenter believes that the proposal “strikes the right balance across all participants.”²⁵

The Commission believes that the proposal is designed to foster cooperation and coordination among the parties engaged in facilitating transactions in securities by setting forth a basic framework within which a Clearing Member can exercise greater control over the use of its clearing services by customers using the services of third party executing brokers in a manner that is not intended to allow for or impose a burden on competition that is not necessary or appropriate in furtherance of the Act. In particular, the Exchange’s proposal will implement a defined and standardized process through which a Clearing Member can “opt in” to limit the use of one or more of its OCC clearing numbers to member organizations that it pre-authorizes in writing, which the Exchange will then enforce through its systems. These provisions are designed to help assure the orderly clearance and settlement of Exchange trades and should, for example, reduce the chance for keypunch errors and may assist Clearing Members in enforcing the provisions of their clearing arrangements with customers.

As an integral and important part of this process, the Exchange will provide notice to affected member organizations, including by providing a 90-day delayed effectiveness on newly restricted OCC numbers, by providing notice to affected member organizations whose authorized status changes, and by providing publicly available information on all Restricted OCC Numbers and the corresponding Clearing Member contact information. In so doing, the proposed rule is designed to promote transparency and provide an orderly process by which third party executing

brokers can make arrangements for clearing services to facilitate transactions on the Exchange.

Further, requiring Clearing Members to use standardized forms to designate all Restricted OCC Numbers and Authorized Member Organizations, and to make amendments to those items, should enhance Phlx’s ability to monitor and enforce compliance with its proposed rule relating to the give up process. Use of standardized forms also may make it easier for Clearing Members and member organizations to comply with the proposed rule, and should benefit all members by providing written confirmation of a member organization’s authorized status with respect to a specific Restricted OCC Number for a particular Clearing Member.

The Commission believes that the proposal seeks to address the needs of different parties involved in facilitating transactions in securities and does so in a balanced manner that provides a reasonable framework for the authorization process. Moreover, the proposal recognizes the need for a member organization to be able to give up its guarantor, and minimizes burdens on the member organization and Clearing Member by allowing such give ups to occur without the need to obtain any further authorization through use of the Clearing Member Restriction Form. In this manner, the proposed rule change recognizes that there will always be a Clearing Member that will be financially responsible for a trade, which should foster operational certainty and facilitate cooperation and coordination with persons engaged in clearing transactions.

For the foregoing reason, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Act²⁶ and the rules and regulations thereunder applicable to national securities exchanges.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,²⁷ that the proposed rule change (SR–Phlx–2018–72) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁸

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019–02895 Filed 2–20–19; 8:45 am]

BILLING CODE 8011–01–P

²⁶ 15 U.S.C. 78f(b)(5).

²⁷ 15 U.S.C. 78s(b)(2).

²⁸ 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85132; File No. SR–NASDAQ–2019–003]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange’s Provisions for Excluding a Day From Its Volume Calculations for Purposes of Determining Tiered Pricing

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b–4 thereunder,² notice is hereby given that on January 31, 2019, The Nasdaq Stock Market LLC (“Nasdaq” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange’s provisions for excluding a day from its volume calculations for purposes of determining tiered pricing.

The text of the proposed rule change is available on the Exchange’s website at <http://nasdaq.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

²² See *supra* note 7.

²³ SIFMA Letter, *supra* note 7, at 2.

²⁴ Davidson Letter, *supra* note 7, at 2.

²⁵ Scott Letter, *supra* note 7, at 1. See also SIFMA Letter, *supra* note 7, at 2.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's provisions for excluding a day from its volume calculations for purposes of determining tiered pricing. The Exchange is standardizing its practice for removing a day from its options volume calculations with its affiliated options market, Nasdaq PHLX ("Phlx").³

To avoid penalizing members when aberrant low volume days result from systems or other issues at the Exchange, or where the Exchange closes early for holiday observance, NOM currently has language in its pricing schedule allowing it to exclude certain days from its average daily volume ("ADV") or other volume calculations.⁴ Currently, language in Options 7, Section 2(5) provides that, for purposes of determining Monthly Volume Tiers under this section, any day that the market is not open for the entire trading day will be excluded from such calculation. The Exchange now proposes to amend this provision by first, renumbering this rule as paragraph (a) to Section 2(5) and second, replacing the term "Monthly Volume Tiers" with "equity tier calculations" to clarify the application of its rule.⁵ The Exchange also proposes to adopt language similar to that on Phlx, which will apply to the options tier calculations in the NOM pricing schedule.⁶ Specifically, the Exchange proposes to adopt a new paragraph (b) to Section 2(5), entitled "Removal of Days for Purposes of Options Pricing Tiers," which will provide:

(i)(A) Any day that the Exchange announces in advance that it will not be open for trading will be excluded from the options tier calculations set forth in its Pricing Schedule; and (B) any day with a scheduled

early market close ("Scheduled Early Close") may be excluded from the options tier calculations only pursuant to paragraph (iii) below.

(ii) The Exchange may exclude the following days ("Unanticipated Events") from the options tier calculations only pursuant to paragraph (iii) below, specifically any day that:

(A) The market is not open for the entire trading day, (B) the Exchange instructs Participants in writing to route their orders to other markets, (C) the Exchange is inaccessible to Participants during the 30-minute period before the opening of trade due to an Exchange system disruption, or (D) the Exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours.

(iii) If a day is to be excluded as a result of paragraph (i)(B) or (ii) above, the Exchange will exclude the day from any Participant's monthly options tier calculations as follows:

(A) The Exchange may exclude from the ADV calculation any Scheduled Early Close or Unanticipated Event; and

(B) the Exchange may exclude from any other applicable options tier calculation provided for in its Pricing Schedule (together with (iii)(A), "Tier Calculations") any Scheduled Early Close or Unanticipated Event.

provided, in each case, that the Exchange will only remove the day for Participants that would have a lower Tier Calculation with the day included.

While similar to the language currently in place on the Exchange, the proposed language: (1) Provides greater flexibility to remove a day in more circumstances, (2) categorizes the potential excluded days into days that are known in advance (*i.e.*, days in proposed paragraph (i), including Scheduled Early Closes), and those that are not (*i.e.*, Unanticipated Events in proposed paragraph (ii)), and (3) modifies the provision so that Participants will only have the day removed when doing so is beneficial for the Participant (*i.e.*, only if the Participant would have a lower volume tier calculation with the day included, hereinafter, the "better of rule"). As it relates to Unanticipated Events, the Exchange will inform all Participants if any such day will be excluded from its Tier Calculations via a system status message disseminated to all Participants. The Exchange notes that it is not proposing to amend the thresholds a Participant must achieve to become eligible for, or the dollar amount associated with, the tiered rebates or fees.

Potential Excluded Days

The Exchange first proposes to adopt language identical to Phlx providing that it will always exclude days where the Exchange announces in advance that it will not be open for trading (*e.g.*,

Thanksgiving) from all options tier calculations set forth in its Pricing Schedule.⁷ This is also the case today since no trading activity occurs on those days, and the Exchange is only clarifying its current practice within the proposed rule.

In addition, Phlx adopted the language on instructing members to route away to prevent situations where days that have artificially lower volume could not be excluded, for example, because the exchange experienced an issue in the morning that did not carry over into the trading day.⁸ Like Phlx, the Exchange believes that it should have the flexibility to exclude days if members have been instructed to send their orders elsewhere, regardless of whether the issue that resulted in this instruction ultimately impacts the availability of the Exchange for trading.

In addition, the Exchange proposes to adopt identical language as on Phlx to exclude days where the Exchange is inaccessible to Participants during the 30-minute period before the opening of trade (*i.e.*, between 9:00 a.m. to 9:30 a.m. Eastern Time) due to an Exchange system disruption.⁹ While the language proposed above on instructing Participants to route away may also cover Exchange system disruptions that occur before the market opens, the Exchange notes that it may not always instruct Participants to route away in such instances. For example, the Exchange may be inaccessible to Participants in the morning due to a systems disruption but the Exchange resolves the issue shortly before 9:30 a.m. and as a result, the Exchange does not instruct Participants to route away. In this instance, the Exchange would not be permitted to exclude the day from its volume calculations. The Exchange generally experiences a high volume of member participation within the 30-minute window leading up to the opening of trade from Participants who submit eligible interest to be included in the Exchange's opening process. As a result, days where Participants are precluded from submitting eligible interest during this 30-minute time period due to an Exchange systems disruption, even if the issue is ultimately resolved by the Exchange before the market opens (and Participants therefore are not instructed to route away), are likely to have lower trading volume. Including such days in calculations of ADV will therefore make it more difficult for Participants to achieve particular pricing tiers for that

³ See Phlx pricing schedule, Options 7, Section 1(b). The Exchange's other affiliated options markets, Nasdaq ISE, Nasdaq GEMX, Nasdaq MRX, and Nasdaq BX will also file similar rule change proposals to conform to Phlx's rule.

⁴ Other volume calculations include certain cross-asset volume tiers that link rebates on NOM to activity on the Nasdaq Stock Market such as the Tier 6 Customer and Professional Rebate to Add Liquidity in Penny Pilot Options. See Options 7, Section 2(1).

⁵ Because the Exchange is conforming its practice for options markets only, the current language will remain in place for the equity tier calculations in the NOM pricing schedule such as the Tier 6 Customer and Professional Rebate to Add Liquidity in Penny Pilot Options described in note 4 above, with the clarifying modifications discussed above.

⁶ See note 3 above.

⁷ See *id.* at paragraph (1)(A).

⁸ See *id.* at paragraph (2)(B).

⁹ See *id.* at paragraph (2)(C).

month. Accordingly, excluding such days from the monthly tier calculations will diminish the likelihood of a cost increase occurring because a Participant is not able to reach a pricing tier on that date that it would reach on other trading days during the month.

The Exchange further proposes to adopt language identical to Phlx to exclude days where there is an Exchange system disruption that lasts for more than 60 minutes during regular trading hours (*i.e.*, 9:30 a.m. to 4:00 p.m. Eastern Time), even if such disruption would not be categorized as a complete outage of the Exchange's system.¹⁰ Such a disruption may occur where a certain options series traded on the Exchange is unavailable for trading due to an Exchange systems issue, or where the Exchange may be able to perform certain functions with respect to accepting and processing orders, but may have a failure to another significant process, such as routing to other market centers, that would lead Participants who rely on such processes to avoid using the Exchange until the Exchange's entire system was operational. The Exchange believes that certain system disruptions that are not complete system outages could preclude some members from submitting orders to the Exchange. The Exchange also notes that this proposal is consistent with the rules of other options exchanges.¹¹

Because the potential excluded days proposed above generally have artificially lower trading volume, the Exchange believes it is reasonable and equitable to exclude such days in determining its options fee and rebate tiers. The Exchange desires to avoid penalizing Participants that might otherwise qualify for certain tiered pricing but that, because of special circumstances on a particular day, did not participate on the Exchange to the extent that they might have otherwise participated. Absent the authority to exclude such days, Participants may experience an effective increase in the cost of trading on NOM, a result that is both unintended and undesirable to the Exchange and to its Participants.

Categories of Excluded Days

In light of the foregoing proposal, the Exchange seeks to categorize the potential excluded days proposed above

between days that are known in paragraph (i) and days that are not in paragraph (ii), and define the latter as Unanticipated Events. For planned days, the Exchange proposes to further distinguish between days that the Exchange announces in advance that it will not be open for trading in paragraph (i)(A) (*e.g.*, Thanksgiving), and Scheduled Early Closes in paragraph (ii)(B) (*e.g.*, the trading day after Thanksgiving). The Exchange notes that it currently considers Scheduled Early Closes as a subset of days that the market is not open for the entire trading day. The Exchange believes it would be more clear to distinguish Scheduled Early Closes in paragraph (i) as a day that is planned for in advance, and separately consider days that are not open for the entire trading day as Unanticipated Events in paragraph (ii)(A). As proposed, (ii)(A) would continue to cover unplanned days where the Exchange declares a trading halt in all securities or honors a market-wide trading halt declared by another market. The other scenarios that will be categorized as Unanticipated Events in paragraph (ii) are days that the Exchange instructs members in writing to route away and the two systems-related disruptions, each as further described above. The foregoing proposal is consistent with how Phlx categorizes potential excluded days today.¹²

Better of Rule

Similar to Phlx, the proposed language also specifies how the potential excluded days will be removed from the Exchange's volume calculations. In particular, the language will allow the Exchange to exclude any Scheduled Early Close or Unanticipated Event from its calculations of ADV or any other applicable options volume tiers provided for in its Pricing Schedule, provided that the Exchange will only remove such days for Participants that would have a lower volume calculation with the day included (*i.e.*, the better of rule).¹³

Phlx adopted the better of rule to avoid penalizing members that step up and trade on days with artificially low volume so that it only excludes such days for members that would have a lower volume calculation with the day included. This language would also be helpful on the Exchange as it would ensure that Participants that continue to

execute a large volume of contracts are not inadvertently disadvantaged when the Exchange removes a day from its volume calculations. Furthermore, Phlx adopted the catch-all provision applying to other options tier calculations set forth in its pricing schedule, but not specified within paragraph (3) of its rule, so that it would have flexibility to apply the better of rule going forward to all options pricing programs administered by the Exchange that are based on volume calculations.¹⁴ The Exchange believes that adopting a similar principle-based approach for its options volume calculations would ensure that days are removed from such calculations only if doing so would be beneficial for the Participant. As such, the proposed language will not apply to straight volume accumulations as Participants do not benefit when a day is removed for such accumulations. Again, the Exchange believes that the approach of Phlx would be beneficial as it counts volume executed during an excluded day toward its members' straight volume accumulations.

In addition, the Exchange proposes to harmonize its language with Phlx's language by adding further detail throughout the proposed rule text to bring greater transparency as to how the Exchange will apply the better of rule when removing days from its tier calculations. First, the Exchange proposes to make clear that it will only remove days pursuant to the better of rule by specifying in paragraphs (i)(B) and (ii) that such days may be excluded from the tier calculations only pursuant to paragraph (iii).¹⁵ Paragraph (iii) will then provide that if a day is to be excluded as a result of paragraph (i)(B) or (ii), the Exchange will be required to exclude the day from any Participant's monthly options tier calculations as detailed within paragraph (iii).¹⁶ With the proposed changes, the Exchange seeks to clarify that it will exclude days from any Participant's tier calculations in a uniform manner to ensure that days are removed only in situations where the Participant benefits. The Exchange will look at each potential excluded day in a month and determine for every Participant their ADV or other applicable volume calculation based on their trading volume on that day. If any Participant would have a lower volume calculation with the particular day included, the Exchange will exclude that day for that Participant. As such,

¹⁰ See *id.* at paragraph 2(D).

¹¹ See BATS BZX Options Exchange Fee Schedule (defining an "Exchange System Disruption" as any day that the exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours); and NYSE Arca Options Fee Schedule (defining an "Exchange System Disruption" as a disruption affects an Exchange system that lasts for more than 60 minutes during regular trading hours).

¹² See note 3 above at paragraphs (1) and (2).

¹³ Phlx similarly excludes Scheduled Early Closes and Unanticipated Events from its ADV calculations and other applicable volume calculations in its pricing schedule, subject in each case to the better of rule. See note 3 above at paragraph (3).

¹⁴ See *id.* at paragraph (3)(C).

¹⁵ See *id.* at paragraphs (1)(B) and (2) for similar language on Phlx.

¹⁶ See *id.* at paragraph (3) for similar language on Phlx.

the proposed changes specify that the Exchange will apply the better of rule in a uniform manner for all Participants, and that there is no arbitrary selection of “winners” or “losers” when the Exchange excludes days.

Equity 7, Section 118

In light of the foregoing proposal to amend the provisions for removing days in Options 7, Section 2, the Exchange proposes to make related changes to its current provisions for removing days in Equity 7, Section 118. Currently, the Exchange has a number of cross-asset volume tiers in its equity pricing schedule, which link reduced transaction fees on the Nasdaq Stock Market to activity on NOM,¹⁷ similar to the rebate tiers on NOM that link to activity on the Nasdaq Stock Market as discussed above.¹⁸ Furthermore, the Exchange has language in Equity 7, Section 118(j) allowing it to exclude certain days from the volume calculations in its equity pricing schedule.¹⁹ The Exchange now seeks to amend Section 118(j) to make clear that this language will continue to apply to the equity tier calculations within Section 118, and the language proposed in Options 7, Section 2(5)(b) will apply to the options tier calculations in Section 118.²⁰

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,²¹ in general, and furthers the

¹⁷ For example, Nasdaq charges a reduced transaction fee of \$0.0029 per share if the member adds Customer, Professional, Firm, Non-NOM Market Maker and/or Broker-Dealer liquidity in Penny Pilot Options and/or Non-Penny Pilot Options of 1.15% or more of total industry ADV in the customer clearing range for Equity and ETF option contracts per day in a month on NOM. See Equity 7, Section 118(a)(1).

¹⁸ See note 4 above. Also, for example, footnote “e” of the NOM pricing schedule provides that NOM Participants that transact in all securities through one or more of its Nasdaq Market Center MPIDs that represent 3.00% or more of Consolidated Volume in the same month on The Nasdaq Stock Market will receive a \$0.52 per contract rebate to add liquidity in Penny Pilot Options as Customer or Professional and \$1.00 per contract rebate to add liquidity in Non-Penny Pilot Options as Customer or Professional. See Options 7, Section 2(1).

¹⁹ In particular, Section 118(j) presently provides that, for purposes of determining average daily volume and total consolidated volume under this section, any day that the market is not open for the entire trading day will be excluded from such calculation. In addition, for purposes of calculating Consolidated Volume and the extent of a member’s trading activity, expressed as a percentage of or ratio to Consolidated Volume, the date of the annual reconstitution of the Russell Investments Indexes shall be excluded from both total Consolidated Volume and the member’s trading activity.

²⁰ See note 17 above.

²¹ 15 U.S.C. 78f(b).

objectives of Sections 6(b)(4) and 6(b)(5) of the Act,²² in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable and equitable as it provides a new framework for removing days from the Exchange’s options volume tier calculations that the Exchange believes is beneficial to Participants and consistent with similar provisions already in place on Phlx. The proposed rule change would allow the Exchange to remove a day from its options volume calculations in more circumstances, and ensures that the Exchange will only do so in circumstances where beneficial for the Participant. The Exchange believes that it is reasonable and equitable to exclude a day from its volume calculations when Participants are instructed to route their orders to other markets as this preserves the Exchange’s intent behind adopting volume-based pricing, and avoids penalizing Participants that follow this instruction.

The Exchange similarly believes it is reasonable and equitable to exclude a day from its volume calculations when the Exchange’s system experiences a disruption during the 30-minute period prior to the opening of trade which renders the Exchange inaccessible to Participants. Without this change, Participants that are precluded from submitting eligible interest during the 30-minute window before the opening of trade may be negatively impacted, even if the Exchange resolves the issue before the market opens and as a result, does not instruct Participants to route away. The proposed change to exclude such days will diminish the likelihood of a cost increase occurring because a member is not able to reach a volume tier calculation on that date that it would reach on other trading days during the month.

Similarly, excluding a day where the Exchange’s system experiences a disruption that lasts for more than 60 minutes intra-day is reasonable and equitable because the proposal seeks to avoid penalizing Participants that might otherwise qualify for certain tiered pricing but that, because of an Exchange systems disruption, did not participate on the Exchange to the extent they might have otherwise participated. The Exchange believes that certain systems disruptions could preclude some

Participants from submitting orders to the Exchange even if such issue is not actually a complete systems outage.

In addition, the Exchange believes that it is reasonable and equitable to only exclude a day from its volume calculations for Participants that would otherwise have a lower volume calculation with the day included. Without these changes, Participants that route away in accordance with the Exchange’s instructions, or that step up and trade significant volume on excluded trading days, may be negatively impacted, resulting in an effective cost increase for those Participants. In addition, having a catch-all in paragraph (iii)(B) so that the better of rule applies to other options volume calculations than ADV to allow the Exchange to apply the rule going forward to all pricing programs based on volume calculations will further protect Participants. The Exchange notes that aberrant low volume days resulting from, for instance, an Unanticipated Event, impacts all volume calculations, and allowing the Exchange to exclude such days from any volume tier calculation if the Participant would have a lower tier calculation with the day included will further protect Participants from being inadvertently penalized.

Furthermore, the Exchange believes that categorizing the potential excluded days is reasonable and equitable because it will bring greater transparency to the application of its rule. Specifically, the Exchange is distinguishing between planned and unplanned days in paragraphs (i) and (ii), defining the latter as Unanticipated Events, and stipulating how the Exchange will exclude such days pursuant to this rule. Categorizing days in this manner will clarify the application of its rule in light of the Exchange’s proposal to expand the rule to adopt additional days that may be excluded from its volume calculations. Providing in paragraph (i)(A) that the Exchange will always exclude from its tier calculations days that it announces in advance it will not be open for trading will clarify current practice. Furthermore, the Exchange believes that the proposed changes to specify how days in paragraphs (i)(B) and (ii) may be excluded from its volume calculations will bring greater transparency by delineating the various circumstances in which the better of rule will apply. Providing in paragraph (iii) that the Exchange may exclude any Scheduled Early Close or Unanticipated Event from the Tier Calculations, subject to the better of rule, will make clear that the Exchange will take a consistent

²² 15 U.S.C. 78f(b)(4) and (5).

approach when excluding days for purposes of its volume based pricing tiers. Furthermore, the proposed changes specifying that the days in paragraphs (i)(B) and (ii) may be excluded only pursuant to paragraph (iii), and requiring the Exchange to exclude such days pursuant to the specifications in paragraph (iii) will likewise make clear that the Exchange will take a consistent approach with respect to excluding days from its Tier Calculations. As discussed above, these modifications will clarify that the Exchange will apply the better of rule in a uniform manner to all Participants, and that there is no arbitrary selection of “winners” or “losers.”

The Exchange also believes that specifying in its equity and options pricing schedules that the proposed rule for excluding days in Options 7, Section 2(5)(b) applies only to options tier calculations, and that the current rules for excluding days²³ continue to apply to the equity tier calculations is reasonable and equitable. As discussed above, the Exchange has a number of cross-asset tiers within its equity and options pricing schedule,²⁴ and believes that the proposed changes will clarify the application of the Exchange’s provisions for excluding days in light of the Exchange’s initiative to standardize its practice across the options markets.

Finally, the Exchange believes that the proposed rule change is not unfairly discriminatory because it will apply equally to all Exchange members that transact on the Nasdaq Stock Market and on NOM. Nasdaq Stock Market members that are not currently Participants on NOM are eligible to become Participants by amending their membership application to add NOM. Moreover, the Exchange notes that any NOM Participant may trade equities on the Nasdaq Stock Market because they are already approved members.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to protect Participants from the possibility of a cost increase by excluding days when overall participation might be significantly lower than a typical trading day. The Exchange believes that the proposed modifications to its tier calculations are pro-competitive and

will result in lower total costs to end users, a positive outcome of competitive markets. Furthermore, other options exchanges have adopted rules that are substantially similar to the Exchange’s proposal.²⁵

The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act²⁶ and paragraph (f) of Rule 19b-4 thereunder.²⁷ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR–NASDAQ–2019–003 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2019–003. 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–NASDAQ–2019–003, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁸

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019–02892 Filed 2–20–19; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–85131; File No. SR–BX–2019–001]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Options 7, Section 2

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”),¹ and Rule 19b-4 thereunder,²

²³ See Equity 7, Section 118(j) and Options 7, Section 2(5)(a).

²⁴ See notes 4, 17, and 18 above.

²⁵ See notes 3 and 11 above.

²⁶ 15 U.S.C. 78s(b)(3)(A)(ii).

²⁷ 17 CFR 240.19b-4(f).

²⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

notice is hereby given that on January 31, 2019, Nasdaq BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Options 7, Section 2, which sets forth fees and rebates for the Exchange’s options market (“BX Options”), to adopt language that allows the Exchange to remove a day from its options volume calculations for purposes of determining pricing tiers.

The text of the proposed rule change is available on the Exchange’s website at <http://nasdaqbx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Today, the Exchange offers a number of pricing incentives based on volume calculations that are designed to encourage participation in BX Options through rebates or reduced fees for Participants that trade on BX Options in increasingly higher volumes.³ The Exchange now proposes to adopt language in Section 2 that would allow it to exclude certain days from such volume calculations for purposes of

determining pricing tiers. The Exchange is standardizing its practice for removing a day from options volume calculations in its Pricing Schedule with its affiliated options market, Nasdaq Phlx (“Phlx”).⁴

Specifically in Options 7, Section 2, the Exchange proposes to adopt new subsection (6) with the title “Removal of Days for Purposes of Pricing Tiers,” which will provide:

(i)(A) Any day that the Exchange announces in advance that it will not be open for trading will be excluded from the options tier calculations set forth in its Pricing Schedule; and (B) any day with a scheduled early market close (“Scheduled Early Close”) may be excluded from the options tier calculations only pursuant to paragraph (iii) below.

(ii) The Exchange may exclude the following days (“Unanticipated Events”) from the options tier calculations only pursuant to paragraph (iii) below, specifically any day that: (A) The market is not open for the entire trading day, (B) the Exchange instructs Participants in writing to route their orders to other markets, (C) the Exchange is inaccessible to Participants during the 30-minute period before the opening of trade due to an Exchange system disruption, or (D) the Exchange’s system experiences a disruption that lasts for more than 60 minutes during regular trading hours.

(iii) If a day is to be excluded as a result of paragraph (i)(B) or (ii) above, the Exchange will exclude the day from any Participant’s monthly options tier calculations as follows:

(A) the Exchange may exclude from the ADV calculation any Scheduled Early Close or Unanticipated Event; and

(B) the Exchange may exclude from any other applicable options tier calculation provided for in its Pricing Schedule (together with (iii)(A), “Tier Calculations”) any Scheduled Early Close or Unanticipated Event.

provided, in each case, that the Exchange will only remove the day for Participants that would have a lower Tier Calculation with the day included.

The proposed language would: (1) Allow the Exchange to remove a day from its volume calculations in Options 7, Section 2⁵ in a number of specified circumstances, which typically result in artificially low volume days, (2) categorize potential excluded days as

those that are known in advance (*i.e.*, days in proposed paragraph (i), including Scheduled Early Closes), and those that are not (*i.e.*, Unanticipated Events in proposed paragraph (ii)), and (3) allow the Exchange to remove a day only when doing so would be beneficial for the Participant (*i.e.*, only if the Participant would have a lower ADV calculation with the day included, hereinafter, the “better of rule”). As it relates to Unanticipated Events, the Exchange will inform all Participants if any such day will be excluded from its Tier Calculations via a system status message disseminated to all Participants. The Exchange notes that it is not proposing to amend the thresholds a Participant must achieve to become eligible for, or the dollar amount associated with, the tiered rebates or fees.

Potential Excluded Days

As noted above, the proposal will allow the Exchange to remove days from Participants’ volume calculations in a number of circumstances that generally result in artificially low volume days. First, the Exchange proposes to adopt language identical to Phlx providing that it will always exclude days where the Exchange announces in advance that it will not be open for trading (*e.g.*, Thanksgiving) from all options tier calculations set forth in its Pricing Schedule.⁶ This is also the case today since no trading activity occurs on those days, and the Exchange is only clarifying its current practice within the proposed rule. Second, the Exchange proposes to adopt language that would permit the Exchange to exclude any Scheduled Early Close from its volume calculations. The Exchange believes that Scheduled Early Closes, which typically are days before or after a holiday, may preclude some Participants from submitting orders to the Exchange at the same level as they might otherwise. This proposal is consistent with the treatment of such days on Phlx.⁷

Third, the Exchange proposes language allowing it to exclude days where the market is not open for the entire trading day, such as days where the Exchange declares a trading halt in all securities or honors a market-wide trading halt declared by another market, because those days typically have lower trading volume. This is consistent with Phlx’s practice for removing such days from its volume calculations.⁸

Fourth, Phlx adopted the language on instructing members to route away to

³ For instance, the Exchange currently offers BX Options Market Makers and Customers tiered rebates and fees for adding or removing liquidity in Penny Pilot and Non-Penny Pilot Options that are based on average daily volume (“ADV”) calculations. See Options 7, Section 2(1).

⁴ See Phlx Pricing Schedule, Options 7, Section 1(b). The Exchange’s other affiliated options markets, Nasdaq ISE, Nasdaq GEMX, Nasdaq MRX, and The Nasdaq Options Market will also file similar rule change proposals to conform to Phlx’s rule.

⁵ See note 3 above.

⁶ See note 4 above at paragraph (1)(A).

⁷ See *id.* at paragraph (1)(B).

⁸ See *id.* at paragraph (2)(A).

prevent situations where days that have artificially lower volume could not be excluded, for example, because Phlx experienced an issue in the morning that ultimately did not carry over into the trading day.⁹ Like Phlx, the Exchange believes that it should have the flexibility to exclude days if Participants have been instructed to send their orders elsewhere, regardless of whether the issue that resulted in this instruction ultimately impacts the availability of the Exchange for trading.

Fifth, the Exchange proposes to adopt identical language as Phlx to exclude days where the Exchange is inaccessible to Participants during the 30-minute period before the opening of trade (*i.e.*, between 9:00 a.m. to 9:30 a.m. Eastern Time) due to an Exchange system disruption.¹⁰ While the language proposed above on instructing Participants to route away may also cover Exchange system disruptions that occur before the market opens, the Exchange notes that it may not always instruct Participants to route away in such instances. For example, the Exchange may be inaccessible to Participants in the morning due to a systems disruption but the Exchange resolves the issue shortly before 9:30 a.m. and as a result, the Exchange does not instruct Participants to route away. In this instance, the Exchange would not be permitted to exclude the day from its volume calculations. The Exchange generally experiences a high volume of member participation within the 30-minute window leading up to the opening of trade from Participants who submit eligible interest to be included in the Exchange's opening process. As a result, days where Participants are precluded from submitting eligible interest during this 30-minute time period due to an Exchange systems disruption, even if the issue is ultimately resolved by the Exchange before the market opens (and Participants therefore are not instructed to route away), are likely to have lower trading volume. Including such days in calculations of ADV will therefore make it more difficult for Participants to achieve particular pricing tiers for that month. Accordingly, excluding such days from the monthly tier calculations will diminish the likelihood of a cost increase occurring because a Participant is not able to reach a pricing tier on that date that it would reach on other trading days during the month.

Sixth, the Exchange proposes to adopt language identical to Phlx to exclude days where there is an Exchange system

disruption that lasts for more than 60 minutes during regular trading hours (*i.e.*, 9:30 a.m. to 4:00 p.m. Eastern Time), even if such disruption would not be categorized as a complete outage of the Exchange's system.¹¹ Such a disruption may occur where a certain options series traded on the Exchange is unavailable for trading due to an Exchange systems issue, or where the Exchange may be able to perform certain functions with respect to accepting and processing orders, but may have a failure to another significant process, such as routing to other market centers, that would lead Participants who rely on such processes to avoid using the Exchange until the Exchange's entire system was operational. The Exchange believes that certain system disruptions that are not complete system outages could preclude some Participants from submitting orders to the Exchange. The Exchange also notes that this proposal is consistent with the rules of other options exchanges.¹²

Because the potential excluded days proposed above generally have artificially lower trading volume, the Exchange believes it is reasonable and equitable to exclude such days in determining its fee and rebate tiers. The Exchange desires to avoid penalizing Participants that might otherwise qualify for certain tiered pricing but that, because of special circumstances on a particular day, did not participate on the Exchange to the extent that they might have otherwise participated. Absent the authority to exclude such days, Participants may experience an effective increase in the cost of trading on BX Options, a result that is both unintended and undesirable to the Exchange and to its Participants.

Categories of Excluded Days

In light of the foregoing proposal, the Exchange seeks to categorize the potential excluded days proposed above between days that are known in paragraph (i) and days that are not in paragraph (ii), and define the latter as Unanticipated Events. Specifically, paragraph (i) would set forth days that the Exchange announces in advance that it will not be open for trading in paragraph (i)(A), and Scheduled Early Closes in paragraph (ii)(B), as further described above. The Unanticipated

Events in paragraph (ii) would cover the days where the Exchange is not open for the entire trading day (*e.g.*, the Exchange declares a trading halt in all securities), days that the Exchange instructs Participants in writing to route away, and the two Exchange systems-related disruptions, each as described above. The foregoing proposal is consistent with how Phlx categorizes potential excluded days today.¹³

Better of Rule

Similar to Phlx, the proposed language also specifies how the potential excluded days will be removed from the Exchange's volume calculations. In particular, the language will allow the Exchange to exclude any Scheduled Early Close or Unanticipated Event from its calculations of ADV or any other applicable options volume tiers provided for in its Pricing Schedule, provided that the Exchange will only remove such days for Participants that would have a lower volume calculation with the day included (*i.e.*, the better of rule).¹⁴

Phlx adopted the better of rule to avoid penalizing members that step up and trade on days with artificially low volume so that it only excludes such days for members that would have a lower volume calculation with the day included. This language would also be helpful on the Exchange as it would ensure that Participants that continue to execute a large volume of contracts are not inadvertently disadvantaged when the Exchange removes a day from its volume calculations. Furthermore, Phlx adopted the catch-all provision applying to other options tier calculations set forth in its pricing schedule, but not specified within paragraph (3) of its rule, so that it would have flexibility to apply the better of rule going forward to all options pricing programs administered by the Exchange that are based on volume calculations.¹⁵ The Exchange believes that adopting a similar principle-based approach for its options volume calculations would ensure that days are removed from such calculations only if doing so would be beneficial for the Participant. As such, the proposed language will not apply to straight volume accumulations as Participants do not benefit when a day is removed for such accumulations. Again, the Exchange believes that the

¹¹ See *id.* at paragraph 2(D).

¹² See BATS BZX Options Exchange Fee Schedule (defining an "Exchange System Disruption" as any day that the exchange's system experiences a disruption that lasts for more than 60 minutes during regular trading hours); and NYSE Arca Options Fee Schedule (defining an "Exchange System Disruption" as a disruption affects an Exchange system that lasts for more than 60 minutes during regular trading hours).

¹³ See note 4 above at paragraphs (1) and (2).

¹⁴ Phlx similarly excludes Scheduled Early Closes and Unanticipated Events from its ADV calculations and other applicable volume calculations in its pricing schedule, subject in each case to the better of rule. See note 4 above at paragraph (3).

¹⁵ See *id.* at paragraph (3)(C).

⁹ See *id.* at paragraph (2)(B).

¹⁰ See *id.* at paragraph (2)(C).

approach of Phlx would be beneficial as it counts volume executed during an excluded day toward its members' straight volume accumulations.

In addition, the Exchange proposes to harmonize its language with Phlx's language by adding further detail throughout the proposed rule text to bring greater transparency as to how the Exchange will apply the better of rule when removing days from its tier calculations. Specifically, the Exchange proposes to make clear that it will only remove days pursuant to the better of rule by specifying in paragraphs (i)(B) and (ii) that such days may be excluded from the tier calculations only pursuant to paragraph (iii).¹⁶ Paragraph (iii) will then provide that if a day is to be excluded as a result of paragraph (i)(B) or (ii), the Exchange will be required to exclude the day from any Participant's monthly options tier calculations as detailed within paragraph (iii).¹⁷ With the proposed changes, the Exchange seeks to clarify that it will exclude days from any Participant's Tier Calculations in a uniform manner to ensure that days are removed only in situations where the Participant benefits. The Exchange will look at each potential excluded day in a month and determine for every Participant their ADV or other applicable volume calculation based on their trading volume on that day. If any Participant would have a lower volume calculation with the particular day included, the Exchange will exclude that day for that Participant. As such, the proposed changes specify that the Exchange will apply the better of rule in a uniform manner for all Participants, and that there is no arbitrary selection of "winners" or "losers" when the Exchange excludes days.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,¹⁸ in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,¹⁹ in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed rule change is reasonable and equitable as it provides a new framework for removing days from the

Exchange's volume calculations that the Exchange believes is beneficial to Participants and consistent with similar provisions already in place on Phlx. The proposed rule change would permit the Exchange to remove a day from its volume calculations in numerous circumstances as described above, and ensures that the Exchange will only do so when beneficial for the Participant. The Exchange believes that it is reasonable and equitable to exclude Scheduled Early Closes from its volume calculations because this preserves the Exchange's intent behind adopting volume-based pricing. Absent the authority to exclude Scheduled Early Closes, Participants may experience an effective increase in fees or decrease in rebates. The artificially low volumes of trading on such days typically reduce the trading activity of Participants. Accordingly, allowing the Exchange to exclude such days from its volume calculations will diminish the likelihood of an effective increase in the cost of trading on BX Options, a result that is unintended and undesirable to the Exchange and to its Participants.

The Exchange equally believes that it is reasonable and equitable to exclude a day when Participants are instructed to route their orders to other markets as this also preserves the Exchange's intent behind adopting volume-based pricing, and avoids penalizing Participants that follow this instruction. The Exchange likewise believes it is reasonable and equitable to exclude a day from its volume calculations when the Exchange's system experiences a disruption during the 30-minute period prior to the opening of trade which renders the Exchange inaccessible to Participants. Without this change, Participants that are precluded from submitting eligible interest during the 30-minute window before the opening of trade may be negatively impacted, even if the Exchange resolves the issue before the market opens and as a result, does not instruct Participants to route away. The proposed change to exclude such days will diminish the likelihood of a cost increase occurring because a Participant is not able to reach a volume tier calculation on that date that it would reach on other trading days during the month.

Similarly, excluding a day where the Exchange's system experiences a disruption that lasts for more than 60 minutes intra-day is reasonable and equitable because the proposal seeks to avoid penalizing Participants that might otherwise qualify for certain tiered pricing but that, because of an Exchange systems disruption, did not participate on the Exchange to the extent they

might have otherwise participated. The Exchange believes that certain systems disruptions could preclude some Participants from submitting orders to the Exchange even if such issue is not actually a complete systems outage.

In addition, the Exchange believes that it is reasonable and equitable to only exclude a day from its volume calculations for Participants that would otherwise have a lower volume calculation with the day included. Without these changes, Participants that route away in accordance with the Exchange's instructions, or that step up and trade significant volume on excluded trading days, may be negatively impacted, resulting in an effective cost increase for those Participants. In addition, having a catch-all in paragraph (iii)(B) so that the better of rule applies to other options volume calculations than ADV to allow the Exchange to apply the rule going forward to all pricing programs based on volume calculations will further protect Participants. The Exchange notes that aberrant low volume days resulting from, for instance, an Unanticipated Event, impacts all volume calculations, and allowing the Exchange to exclude such days from any volume tier calculation if the Participant would have a lower tier calculation with the day included will further protect Participants from being inadvertently penalized.

Furthermore, the Exchange believes that categorizing the potential excluded days is reasonable and equitable because it will bring greater transparency to the application of its rule. Specifically, the Exchange is distinguishing between planned and unplanned days in paragraphs (i) and (ii), defining the latter as Unanticipated Events, and stipulating how the Exchange will exclude such days pursuant to this rule. Categorizing days in this manner will clarify the application of its rule in light of the Exchange's proposal to adopt numerous days that may be excluded from its volume calculations. Providing in paragraph (i)(A) that the Exchange will always exclude from its tier calculations days that it announces in advance it will not be open for trading will clarify current practice. Furthermore, the Exchange believes that the proposed changes to specify how days in paragraphs (i)(B) and (ii) may be excluded from its volume calculations will bring greater transparency by delineating the various circumstances in which the better of rule will apply. Providing in paragraph (iii) that the Exchange may exclude any Scheduled Early Close or Unanticipated Event from

¹⁶ See *id.* at paragraphs (1)(B) and (2) for similar language on Phlx.

¹⁷ See *id.* at paragraph (3) for similar language on Phlx.

¹⁸ 15 U.S.C. 78f(b).

¹⁹ 15 U.S.C. 78f(b)(4) and (5).

the Tier Calculations, subject to the better of rule, will make clear that the Exchange will take a consistent approach when excluding days for purposes of its volume based pricing tiers. Furthermore, the proposed changes specifying that the days in paragraphs (i)(B) and (ii) may be excluded only pursuant to paragraph (iii), and requiring the Exchange to exclude such days pursuant to the specifications in paragraph (iii) will likewise make clear that the Exchange will take a consistent approach with respect to excluding days from its Tier Calculations. As discussed above, these modifications will clarify that the Exchange will apply the better of rule in a uniform manner to all Participants, and that there is no arbitrary selection of “winners” or “losers.”

Finally, the Exchange believes that the proposed rule change is not unfairly discriminatory because it will apply equally to all Participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to protect Participants from the possibility of a cost increase by excluding days when overall participation might be significantly lower than a typical trading day. The Exchange believes that the proposed modifications to its tier calculations are pro-competitive and will result in lower total costs to end users, a positive outcome of competitive markets. Furthermore, other options exchanges have adopted rules that are substantially similar to the Exchange's proposal.²⁰

The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed fee changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act²¹ and paragraph (f) of Rule 19b-4 thereunder.²² At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-2019-001 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-BX-2019-001. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet 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-BX-2019-001, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02891 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85145; File No. SR-NYSE-2019-03]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to (1) Delete Dealings and Settlements (Rule 45-299C), Rule 235 (Ex-Dividend, Ex-Rights), Rule 236 (Ex-Warrants), and Rule 257 (Deliveries After “Ex” Date) and (2) Amend Dealings and Settlements (Rule 45-299C), Rule 235T (Ex-Dividend, Ex-Rights), Rule 236T (Ex-Warrants), and Rule 257T (Deliveries After “Ex” Date)

February 14, 2019.

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 February 4, 2019, New York Stock Exchange LLC (“NYSE” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to (1) delete Dealings and Settlements (Rule 45-

²³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

²¹ 15 U.S.C. 78s(b)(3)(A)(ii).

²² 17 CFR 240.19b-4(f).

²⁰ See notes 4 and 12 above.

299C), Rule 235 (Ex-Dividend, Ex-Rights), Rule 236 (Ex-Warrants), and Rule 257 (Deliveries After “Ex” Date) and (2) amend Dealings and SettlementsT (Rule 45–299C), Rule 235T (Ex-Dividend, Ex-Rights), Rule 236T (Ex-Warrants), and Rule 257T (Deliveries After “Ex” Date) to reflect the standard settlement cycle in Securities Exchange Act Rule 15c6–1(a). The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to (1) delete Dealings and Settlements (Rule 45–299C), Rule 235 (Ex-Dividend, Ex-Rights), Rule 236 (Ex-Warrants), and Rule 257 (Deliveries After “Ex” Date) and (2) amend Dealings and SettlementsT (Rule 45–299C), Rule 235T (Ex-Dividend, Ex-Rights), Rule 236T (Ex-Warrants), and Rule 257T (Deliveries After “Ex” Date) to reflect the standard settlement cycle in Securities Exchange Act (the “Act”) Rule 15c6–1(a) (“Rule 15c6–1(a)”).

Background

On September 28, 2016, the Securities and Exchange Commission (“SEC”) proposed amendments to Rule 15c6–1(a) to shorten the standard settlement cycle from T+3 to T+2.⁴ The amendment was adopted on March 22, 2017, with a compliance date of September 5, 2017.⁵

In response, the Exchange adopted new rules with the modifier “T” to

reflect a T+2 settlement cycle.⁶ Because the Exchange would not implement the new rules until after the final implementation of T+2, the Exchange retained the versions of the rules reflecting T+3 settlement on its books. Certain of these rules were deleted in connection with the Exchange’s elimination of non-regular way trading.⁷

In order to reduce the potential for confusion regarding which version of the rule governs, the Exchange added explanatory preambles. In particular, the following preamble was added to Dealings and Settlements, Rule 235, Rule 236 and Rule 257:

“This version of . . . will remain operative until the Exchange files separate proposed rule changes as necessary to establish the operative date of . . . , to delete this version of . . . and preamble, and to remove the preamble text from the version of In addition to filing the necessary proposed rule changes, the Exchange will announce via Information Memo the operative date of the deletion of this Rule and implementation of”

The following preamble was added to Dealings and SettlementsT, Rule 235T, Rule 236T and Rule 257T:

“The Exchange will file separate proposed rule changes to establish the operative date of . . . , to delete . . . and the preamble text from . . . , and to remove the preamble text from the version of Until such time, . . . will remain operative. In addition to filing the necessary proposed rule changes, the Exchange will announce via Information Memo the implementation of this Rule and the operative date of the deletion of”

In July 2017, the Exchange (1) deleted Rule 282.65 and Section 703.02(part2) of the Listed Company Manual; (2) deleted the preamble and “T” modifier from Rule 282.65T and Section 703.02T of the Listed Company Manual; and (3) established the operative date of Rule 282.65T and Section 703.02T of the Listed Company Manual.⁸ As part of that filing, the Exchange inadvertently omitted Dealings and Settlements and Dealings and SettlementsT, Rule 235 and Rule 235T, Rule 236 and Rule 236T, and Rule 257 and Rule 257T.

⁶ See Securities Exchange Act Release No. 80021 (February 10, 2017), 82 FR 10931 (February 16, 2017) (SR–NYSE–2016–87).

⁷ See Securities Exchange Act Release No. 81176 (July 20, 2017), 82 FR 34728 (July 26, 2017) (SR–NYSE–2017–33).

⁸ See Securities Exchange Act Release No. 81231 (July 27, 2017), 82 FR 36008 (August 2, 2017) (SR–NYSE–2017–38).

Proposed Rule Change

In order to reflect the September 5, 2017 transition to T+2 settlement in its rulebook, the Exchange proposes to:

- Delete Dealings and Settlements, Rule 235, Rule 236, and Rule 257, including the preambles, in their entirety as obsolete;
- delete the obsolete “T” modifier in Dealings and SettlementsT, Rule 235T, Rule 236T, and Rule 257T; and
- delete the preambles to Dealings and SettlementsT, Rule 235T, Rule 236T, and Rule 257T, which distinguished such rules from the T+3 rules, as obsolete.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and further the objectives of Section 6(b)(5) of the Act,¹⁰ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In particular, the Exchange believes that the proposed changes remove impediments to and perfect the mechanism of a free and open market by adding clarity as to which rules are operative and when, thereby reducing potential confusion, and making the Exchange’s rules easier to navigate. The Exchange also believes that eliminating obsolete material from its rulebook also removes impediments to and perfects the mechanism of a free and open market by removing confusion that may result from having obsolete material in the Exchange’s rulebook. The Exchange believes that eliminating such obsolete material would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency, thereby reducing potential confusion.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather serve to promote clarity and consistency, thereby reducing burdens

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

⁴ See Securities Exchange Act Release No. 78962 (September 28, 2016), 81 FR 69240 (October 5, 2016) (File No. S7–22–16).

⁵ See Securities Exchange Act Release No. 80295 (March 22, 2017), 82 FR 15564 (March 29, 2017) (File No. S7–22–16).

on the marketplace and facilitating investor protection.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 Act¹¹ and Rule 19b-4(f)(6) thereunder.¹²

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹³ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹⁴ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. According to the Exchange, waiver would allow the Exchange to conform the rule to the current settlement cycle and eliminate outdated references to the T+3 settlement cycle without undue delay. The Commission believes that the proposed rule change raises no new or novel issues and that waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.¹⁵

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings 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:

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-NYSE-2019-03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090. All submissions should refer to File Number SR-NYSE-2019-03. 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-NYSE-2019-03 and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Eduardo A. Aleman,
Deputy Secretary.

[FR Doc. 2019-02899 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-85133; File No. SR-BOX-2019-03]

Self-Regulatory Organizations; BOX Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Options Market LLC ("BOX") Facility To Modify Its Strategy QOO Order Fee Cap and Rebate

February 14, 2019.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on February 1, 2019, BOX Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the Fee Schedule to amend the Fee Schedule [sic] on the BOX Options Market LLC ("BOX") options facility. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room

¹⁶ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

¹¹ 15 U.S.C. 78s(b)(3)(A).

¹² 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹³ 17 CFR 240.19b-4(f)(6).

¹⁴ 17 CFR 240.19b-4(f)(6)(iii).

¹⁵ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

and also on the Exchange's internet website at <http://boxexchange.com>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule for trading on BOX to amend Section II.D (Strategy QOO Order Fee Cap and Rebate). Currently, the Exchange caps fees and offers rebates on all reversal, conversion, jelly roll, and box spread strategies on the BOX Trading Floor. The Exchange is now proposing to cap fees and offer a Floor Broker rebate for short stock interest strategy transactions.

A short stock interest strategy is a transaction done to achieve a short stock interest arbitrage involving the purchase, sale, and exercise of in-the-money options of the same class. The Exchange proposes to include this definition in a footnote in the BOX Fee Schedule along with the other definitions of the strategies in Section II.D.

The Exchange proposes to offer a strategy cap for short stock interest strategies. Today, Floor Participant transactions are capped at \$1,000 for all reversal, conversion, jelly roll, and box spread strategies executed on the same trading day.⁵ The Exchange proposes to include short stock interest strategies in the daily Strategy QOO Order Fee Cap and Rebate. As such, Floor Participant transactions will also be capped at \$1,000 for all short stock interest strategies executed on the same trading day. Further, the Exchange proposes to include short stock interest strategies in the Floor Broker Strategy QOO Rebate. As proposed, on each trading day, Floor Brokers are eligible to receive a \$500 rebate for presenting certain Strategy

QOO Orders on the Trading Floor. The rebate will be applied once the \$1,000 fee cap for all short stock interest, reversal, conversion, jelly roll, and box spread strategies is met.

The Exchange notes that the fee cap discussed herein exists at another options exchange in the industry.⁶

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,⁷ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that including short stock interest strategies in Section II.D of the BOX Fee Schedule is reasonable, as another exchange offers fee caps for short stock interest strategies, namely Cboe.⁸ Moreover, the Exchange believes the proposed fees are reasonable in comparison because BOX's fee cap for short stock interest strategies is identical to Cboe's fee cap. Further, the Exchange believes that including short stock interest strategies in the Strategy QOO Order rebate is appropriate as Floor Brokers are eligible to receive a \$500 rebate for presenting all other strategies to the BOX Trading Floor.

The Exchange believes that the proposed fee cap for short stock interest strategies is equitable and not unfairly discriminatory because it provides incentives for all Participants to submit these types of strategy orders to the BOX Trading Floor, which brings increased liquidity and order flow to the floor for the benefit of all market participants. Further, the Exchange believes that including short stock interest strategies in the Strategy QOO Order rebate is equitable and not unfairly discriminatory as the rebate is available to all Floor Brokers who submit such orders to the BOX Trading Floor.

⁶ See Cboe Exchange Inc. ("Cboe") Fee Schedule Footnote 13. At Cboe, market-maker, Clearing Trading Permit Holder, JBO participant, broker-dealer and non-Trading Permit Holder market-maker transaction fees are capped at \$1,000 for all short stock interest strategies. Unlike Cboe, BOX does not have a monthly fee cap because the Exchange previously removed it for being unnecessary due to the fact that if Participants are capped at \$1,000 per day, they would never reach the previous \$25,000 monthly fee cap. See SR-BOX-2018-11.

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ See *supra* note 6.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition in furtherance of the purposes of the Act because the proposed change applies uniformly to all Participants that incur transaction fees for short stock interest strategies. Further, another options exchange today offer caps on short stock interest strategies; therefore, the Exchange believes that the proposal is consistent with robust competition and does not provide any unnecessary burden on competition. Further, because Floor Participants pay Floor Brokers to execute trades on the Exchange floor, the Exchange believes that offering fee caps on short stock interest strategies to Participants executing floor transactions and not electronic executions does not create an unnecessary burden on competition because the fee cap defrays brokerage costs associated with executing short stock interest strategy transactions, similar to other strategies today.

The Exchange operates in a highly competitive market in which market participants can easily and readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or rebates to be inadequate. Accordingly, the fee cap and Floor Broker rebate for short stock interest strategies proposed by the Exchange, as described in the proposal, are influenced by these robust market forces and therefore must remain competitive with fee caps at other venues and therefore must continue to be reasonable and equitably allocated to those Participants that opt to direct orders to the Exchange rather than competing venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act⁹ and Rule 19b-4(f)(2) thereunder,¹⁰ because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may

⁹ 15 U.S.C. 78s(b)(3)(A)(ii).

¹⁰ 17 CFR 240.19b-4(f)(2).

⁵ Reversal, conversion, jelly roll and box spread transactions are not included in the monthly fee cap for Broker Dealers.

temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BOX-2019-03 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-BOX-2019-03. 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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. 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-BOX-2019-03, and should be submitted on or before March 14, 2019.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2019-02893 Filed 2-20-19; 8:45 am]

BILLING CODE 8011-01-P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 558 (Sub-No. 22)]

Railroad Cost of Capital—2018

AGENCY: Surface Transportation Board.

ACTION: Notice of decision instituting a proceeding to determine the railroad industry's 2018 cost of capital.

SUMMARY: The Board is instituting a proceeding to determine the railroad industry's cost of capital for 2018. The decision solicits comments on the following issues: The railroads' 2018 current cost of debt capital; the railroads' 2018 current cost of preferred equity capital (if any); the railroads' 2018 cost of common equity capital; and the 2018 capital structure mix of the railroad industry on a market value basis. Comments should focus on the various cost-of-capital components listed above using the same methodology followed in *Railroad Cost of Capital—2017*, EP 558 (Sub-No. 21) (STB served Dec. 6, 2018).

DATES: Notices of intent to participate are due by April 1, 2019. Statements of the railroads are due by April 22, 2019. Statements of other interested persons are due by May 13, 2019. Rebuttal statements by the railroads are due by June 3, 2019.

ADDRESSES: Comments may be submitted either via the Board's e-filing system or in the traditional paper format. Any person using e-filing should comply with the instructions at the E-FILING link at www.stb.gov. Any person submitting a filing in the traditional paper format should send an original and 10 copies to: Surface Transportation Board, Attn: Docket No. EP 558 (Sub-No. 22), 395 E Street SW, Washington, DC 20423-0001.

FOR FURTHER INFORMATION CONTACT: Pedro Ramirez at (202) 245-0333. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1-800-877-8339.

¹¹ 17 CFR 200.30-3(a)(12).

SUPPLEMENTARY INFORMATION: The Board's decision is posted at www.stb.gov. Copies of the decision may be purchased by contacting the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245-0238. Assistance for the hearing impaired is available through FIRS at 1-800-877-8339.

Authority: 49 U.S.C. 10704(a).

Decided: February 14, 2019.

By the Board, Board Members Begeman, Fuchs, and Oberman.

Aretha Laws-Byrum,
Clearance Clerk.

[FR Doc. 2019-02957 Filed 2-20-19; 8:45 am]

BILLING CODE 4915-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Specific Release Form

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information garnered from a Specific Release Form will be used by FAA Special Agents to obtain information related to a specific investigation. That information is then provided to the FAA decision making authority to make FAA employment and/or pilot certification/revocation determinations.

DATES: Written comments should be submitted by April 22, 2019.

ADDRESSES: Send comments to the FAA at the following address: Barbara Hall, Federal Aviation Administration, ASP-110, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized 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.

FOR FURTHER INFORMATION CONTACT:

Barbara Hall by email at: Barbara.L.Hall@faa.gov; phone: 940-594-5913.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2120-0740.

Title: Specific Release Form.

Form Numbers: FAA 1600.81.

Type of Review: Renewal of information collection.

Background: Investigations are conducted under 49 U.S.C. 106, 40113, 40114, 46101, and 46104, the Aviation Drug Trafficking Control Act of 1984, the Anti-Drug Abuse Act of 1986, and the Anti-Drug Abuse Act of 1988. The public respondents are pilots or FAA job applicants from whom additional information is needed to complete a thorough investigation. The information garnered from a signed Specific Release form is used by FAA Special Agents to obtain information related to a specific investigation.

Respondents: Approximately 270 subjects of investigations.

Frequency: Information is collected as needed.

Estimated Average Burden per

Response: 5 minutes.

Estimated Total Annual Burden: 23 hours.

Issued in Washington, DC, on February 15, 2019.

Barbara L. Hall,

FAA Information Collection Clearance Officer, Performance, Policy, and Records Management Branch, ASP-110.

[FR Doc. 2019-02982 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2014-0216; FMCSA-2015-0322; FMCSA-2015-0323; FMCSA-2016-0007]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 12 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have "no established medical

history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV." The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA-2014-0216; FMCSA-2015-0322; FMCSA-2015-0323; FMCSA-2016-0007 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2014-0216; FMCSA-2015-0322; FMCSA-2015-0323; FMCSA-2016-0007), indicate the specific section of this document to which each comment applies, and

provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA-2014-0216; FMCSA-2015-0322; FMCSA-2015-0323; FMCSA-2016-0007, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-2014-0216; FMCSA-2015-0322; FMCSA-2015-0323; FMCSA-2016-0007, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for up to five years if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

The 12 individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315, each of the 12 applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The 12 drivers in this

notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous two-year exemption period. In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License Information System (CDLIS) and the Motor Carrier Management Information System (MCMIS) are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency (SDLA). These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of November and are discussed below.

As of November 4, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers: Joseph Celdonia (MD); and Thomas K. Mitchell (MS).

The drivers were included in docket number FMCSA–2014–0216. Their exemptions are applicable as of November 4, 2018, and will expire on November 4, 2020.

As of November 15, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Kevin Beamon (NY)
Joseph Drion (MO)
Marvin L. Fender (CO)
Robert W. Goddard (NH)
Michael C. Grant (SC)
Todd W. Hines (OH)
John A. Kangas (MI)
Chad T. Knott (MD)
Curt Palubicki (MN)
William M. Powderly (MN)

The drivers were included in docket numbers FMCSA–2015–0322; FMCSA–2015–0323 and FMCSA–2016–0007. Their exemptions are applicable as of November 15, 2018, and will expire on November 15, 2020.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must remain seizure-free and maintain a stable treatment during the two-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the 12 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: February 1, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019–02964 Filed 2–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–2006–25290]

Commercial Driver's License Standards: Application for Exemption; Isuzu North America Corporation (Isuzu)**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.**ACTION:** Notice of final disposition; granting of application for exemption.

SUMMARY: FMCSA announces its decision to approve Isuzu North America Corporation's (Isuzu) application for an exemption from the Federal requirement to hold a U.S. commercial driver's license (CDL) issued by one of the States. The exemption allows 12 Isuzu commercial motor vehicle (CMV) drivers, who are citizens and residents of Japan and hold a Japanese commercial license, to test-drive Isuzu CMVs in the United States without a CDL issued by one of the States. Isuzu requested the exemption so that these driver-employees, as a team, can help to evaluate and test production and prototype Isuzu CMVs for sale in this country. FMCSA believes the knowledge and skills training and testing that drivers must undergo to obtain a Japanese commercial license ensures a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: This exemption is effective February 21, 2019 and expires February 21, 2024.

ADDRESSES: *Docket:* For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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: Ms. Pearlle Robinson, FMCSA Driver and Carrier Operations Division; Office of

Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4325. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:**I. Public Participation***Viewing Comments and Documents*

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, “FMCSA–2006–25290” in the “Keyword” box and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

Isuzu applied for an exemption from the CDL rules, specifically the licensing requirements for drivers operating CMVs in interstate or intrastate

commerce (49 CFR 383.23). Isuzu requested the exemption for 12 driver-employees who are citizens and residents of Japan, and cannot apply for a CDL due to lack of residency in the United States. Isuzu explained that the exemption would allow a team of 12 employees (vehicle test engineers, technicians, mechanics and other employees) to test drive and evaluate production and prototype CMVs on U.S. highways under various environmental and climatic conditions. According to Isuzu, these drivers will not transport merchandise. Each driver holds a valid Japanese commercial license, and as explained by Isuzu in previous exemption requests, applicants for a Japanese commercial license must undergo a training program and pass knowledge and skills tests. A copy of Isuzu's application for exemption is available for review in the docket for this notice.

IV. Method To Ensure an Equivalent or Greater Level of Safety

These Isuzu drivers are experienced CMV operators. In Japan, drivers must hold a conventional driver's license for at least 3 years to be eligible for a commercial license. They must also pass both skills and knowledge tests. A driver granted a Japanese commercial license may legally operate any CMV allowed on the roads of Japan. Isuzu believes that these drivers will achieve a level of safety that equals or exceeds the level of safety that would be achieved without the exemption.

V. Public Comments

On October 19, 2018, FMCSA published notice of this application and requested public comments (83 FR 53151). Three individuals submitted comments, two opposing the exemption. Both said that Isuzu should hire U.S. drivers and voiced concerns over the effects of a perceived language barrier. The third comment was not relevant to the exemption.

VI. FMCSA Response and Decision

FMCSA has previously determined that the process for obtaining a Japanese commercial license is comparable to, or as effective as, the Federal CDL knowledge and skills requirements of 49 CFR part 383 as enforced by the States, and adequately assesses the driver's ability to operate CMVs in the U.S. Since 2003, FMCSA has granted Isuzu drivers similar exemptions [October 16, 2003 (68 FR 59677); April 3, 2007 (72 FR 15933); April 5, 2007 (72 FR 16870); September 5, 2008 (73 FR 51878); January 5, 2009 (74 FR 334); July 24, 2009 (74 FR 36809)].

FMCSA believes that the operations of the 12 Isuzu driver-employees will ensure a level of safety that is equivalent to, or greater than, the level of safety that would be achieved without the exemption. FMCSA's decision to grant this exemption is based on the merits of the application and the considerable CMV driving experience of these drivers. In addition, FMCSA considers the rigorous skills and knowledge testing that drivers undergo to obtain a Japanese commercial license to be comparable to, or as effective as, the requirements of a U.S. CDL (49 CFR part 383). Therefore, FMCSA grants exemption from the requirements of 49 CFR 383.23 to the following 12 individuals while employed by Isuzu, to enable them to operate CMVs in this country without a CDL for a period of 5 years: Naoto Morimoto, Kenji Sugawara, Ryota Hisamatsu, Takehiro Oshima, Yasuhiro Sakai, Hiroaki Takahashi, Kazunori Aizawa, Atsushi Fujiwara, Kazuya Takahashi, Koichi Ueno, Takahisa Chiba, and Takamasa Ono.

VII. Terms and Conditions of the Exemption

This exemption is subject to the following terms and conditions: (1) These drivers are subject to the drug and alcohol regulations, including testing, as provided in 49 CFR part 382, (2) these drivers are subject to the same driver disqualification rules under 49 CFR parts 383 and 391 that apply to other CMV drivers in the United States, (3) Isuzu shall notify FMCSA in writing if an exempted driver is convicted of a disqualifying offense described in sections 383.51 or 391.15 of the Federal Motor Carrier Safety Regulations (49 CFR 350 *et seq.*), (4) these drivers must keep, at all times, a copy of the exemption with them in the CMV they are driving, and (5) Isuzu must notify FMCSA in writing of any accident, as defined in 49 CFR 390.5, that involves an exempted driver.

FMCSA will revoke this exemption if: (1) The Isuzu drivers fail to comply with the terms and conditions of the exemption, (2) the exemption results in a lower level of safety than was maintained before it was granted, or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31315 and 31136.

VIII. Preemption

In accordance with 49 U.S.C. 31315(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate or intrastate commerce that

conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption.

Issued on: February 13, 2019.

Raymond P. Martinez,
Administrator.

[FR Doc. 2019-02950 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2018-0137]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 30 individuals for an exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions would enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2018-0135 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket number(s) for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or

comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE, Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments online.

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

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the FMCSRs for a five-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The 30 individuals listed in this notice have requested an exemption from the hearing requirement in 49 CFR 391.41(b)(11). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a

CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

On February 1, 2013, FMCSA announced in a Notice of Final Disposition titled, Qualification of Drivers; Application for Exemptions; National Association of the Deaf, (78 FR 7479), its decision to grant requests from 30 individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers. Since the February 1, 2013 notice, the Agency has published additional notices granting requests from hard of hearing and deaf individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers.

II. Qualifications of Applicants

Maurice N. Abenchuchan

Mr. Abenchuchan, age 61, holds an operator's license in Florida.

Gary Abendroth

Mr. Abendroth, age 43, holds an operator's license in Wisconsin.

Ronnie R. Adkins

Mr. Adkins, age 62, holds a class A CDL in Missouri.

Brigit Anne Alm

Ms. Alm, age 63, holds an operator's license in Wisconsin.

Prince K. Bempong

Mr. Bempong, age 30, holds an operator's license in Texas.

Kenneth Bilodeau

Mr. Bilodeau, age 38, holds an operator's license in Texas.

William B. Britt

Mr. Britt, age 47, holds an operator's license in Tennessee.

James A. Bryan

Mr. Bryan, age 35, holds an operator's license in Arkansas.

Shawn R. Carico

Mr. Carico, age 23, holds an operator's license in Tennessee.

Gillia J. Cobb

Mr. Cobb, age 32, holds an operator's license in California.

Perry Lynn Cobb

Mr. Cobb, age 43, holds an operator's license in Tennessee.

George P. Cuadera

Mr. Cuaderr, age 42, holds an operator's license in Maryland.

Donte Darrington

Mr. Darrington, age 27, holds an operator's license in Missouri.

Kevin A. Dent

Mr. Dent, age 38, holds an operator's license in Mississippi.

Thomas Garro

Mr. Garro, age 72, holds an operator's license in Arizona.

John L. Gonzagowski

Mr. Gonzagowski, age 81, holds a class A CDL in Missouri.

Marc Graham

Mr. Graham, age 40, holds an operator's letter in California.

Jacob D. Hamilton

Mr. Hamilton, age 30, holds an operator's license in Indiana.

Robert R. Hefner

Mr. Hefner, age 40, holds a class A CDL in South Carolina.

Dwayne Johnson

Mr. Johnson, age 26, holds an operator's license in Illinois.

Marina S. Hernandez

Ms. Hernandez, age 55, holds an operator's license in New Jersey.

Patrick L. Johnson

Mr. Johnson, age 31, holds an operator's license in Michigan.

Justin Kilgore

Mr. Kilgore, age 37, holds a class A CDL in Iowa.

Lawrence Hung K. Lam

Mr. Lam, age 38, holds on operator's license in California.

John N. McKee

Mr. McKee, age 59, holds a class A CDL in Iowa.

John Rhoades

Mr. Roades, age 53, holds an operator's license in Idaho.

Darryl Rutland

Mr. Rutland, age 54, holds an operator's license in California.

Phillip Shook Jr.

Mr. Shook, age 53, holds an operator's license in Mississippi.

Shana Williamson

Ms. Williamson, age 52, holds an operator's license in Texas.

Carl E. Wood

Mr. Wood, age 77, holds a class A CDL in Louisiana.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the dates section of the notice.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-2018-0137 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and materials received during the comment period. FMCSA may issue a final determination any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, go to <http://www.regulations.gov> and in the search box insert the docket number

FMCSA–2018–0137 and click “Search.” Next, click “Open Docket Folder” and you will find all documents and comments related to this notice.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019–02951 Filed 2–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2010–0027]

Hours of Service of Drivers: WestRock, Application for Renewal of Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for renewal of exemption; request for comments.

SUMMARY: WestRock, formerly known as RockTenn has requested a renewal of its exemption from certain provisions of the hours-of-service (HOS) requirements for drivers of property-carrying vehicles. WestRock currently holds an exemption for the period April 17, 2014, through April 16, 2019 for 11 shipping department employees and occasional substitute commercial driver’s license (CDL) holders who transport paper mill products over a 275-foot stretch of public road between its shipping and receiving locations. WestRock requested an exemption from the 14-hour rule and the requirement for 10 consecutive hours off duty before the start of the workday. The renewal of the exemption would allow these individuals occasionally to drive after the 14th hour after coming on duty and allow them to return to work following eight consecutive hours off-duty. FMCSA requests public comment on WestRock’s application for exemption.

DATES: If granted, this exemption would be effective during the period of April 17, 2019 through April 16, 2024. Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments identified by Federal Docket Management System Number FMCSA–2010–0027 by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building,

Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Instructions: All submissions must include the Agency name and docket number. For detailed instructions on submitting comments and additional information on the exemption process, see the *Public Participation* heading below. Note that all comments received will be posted without change to www.regulations.gov, including any personal information provided. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments received, go to www.regulations.gov, and follow the online instructions for accessing the dockets, or go to the street address listed above.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

Public participation: The Federal eRulemaking Portal is available 24 hours each day, 365 days each year. You can obtain electronic submission and retrieval help and guidelines under the “help” section of the Federal eRulemaking Portal website. If you want us to notify you that we received your comments, please include a self-addressed, stamped envelope or postcard, or print the acknowledgement page that appears after submitting comments online.

FOR FURTHER INFORMATION CONTACT: Ms. Pearlle Robinson, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: 202–366–4225. Email: MCPSD@dot.gov. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this

notice (FMCSA–2010–0027), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number, “FMCSA–2010–0027” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may grant or not grant this application based on your comments.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to www.regulations.gov and insert the docket number, “FMCSA–2010–0027” in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button and choose the document listed to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also

provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. WestRock Application for Exemption

WestRock (USDOT 153734) operates a paper mill located in Chattanooga, Tennessee, its principal place of business. Its shipping and receiving departments are on opposite sides of the paper mill, requiring driver/employees to travel on a public road to shuttle trailers as needed. These drivers utilize this public road—Compress Street—an average of forty times per day to go from their shipping to receiving department and to load their trailers in the shipping department. These drivers do not transport any material farther than the paper mill lots and/or Compress Street. The distance traveled on Compress Street is approximately 275 feet in one direction, and one tractor is used to perform this work. Because the material being transported is received from or destined for other States, the local travel is interstate in nature.

The initial WestRock exemption application for relief from the HOS rule was submitted in 2009; a copy of the application is in the docket. That application fully described the nature of shipping operations encountered by CMV drivers employed by WestRock. On May 29, 2012, FMCSA granted WestRock the proposed exemption (77 FR 31684). FMCSA has since renewed this limited exemption [April 22, 2014 (77 FR 22571; and July 25, 2016 (81 FR 48496)]. The current exemption expires on April 16, 2019.

WestRock's shipping department currently works 12-hour shifts for 4 days, and then allows employees 4 days off duty. The schedule is subject to change. Usually there are two shipping department employees on each shift. One employee drives a fork-lift truck loading trailers with finished goods, and

the other operates the tractor shuttling trailers. These employees do not drive a CMV continuously during their shift(s).

At times, WestRock may operate on three 8-hour shifts with employees working a double (16-hour) shift when "rotating back." According to WestRock, the problem arises because of the double-shift, and also on occasion when a shipping department driver does not report for work as scheduled. On a Monday, for example, if an individual worked the weekend, his or her shift would normally have to "hurry back" within 8 hours. As a result of the mandatory 10 hours off-duty requirement for drivers, without the exemption WestRock would be required to schedule these drivers' shifts to start later than other employees. This would create at least 2 hours when the company cannot load or transport trailers with finished goods due to the absence of the drivers. Furthermore, as a result of the 14-hour driving windows, they would "work short" without the exemption, creating on-time delivery issues for other employees, who are allowed to work an entire "double shift" (16 hours) when necessary.

WestRock requested renewal of its exemption from 49 CFR part 395 for its shipping department CMV drivers, as well as others with a valid CDL who on occasion must substitute, allowing all such drivers to drive as late as the 16th hour since coming on duty and return to work with a minimum of at least 8 hours off duty. If exempt from the normal HOS requirements, these employees could follow the same work schedule as other WestRock employees on their shift, and would be able to work for the full 16 hours of a "double shift." WestRock could therefore minimize the chances of delayed shipments that might occur if their drivers were not allowed to work the same schedule as other employees.

WestRock acknowledged in its application that these drivers would still be subject to all of the other FMCSRs, including possessing a CDL, random drug testing, medical certification, and other driver-qualification requirements.

A copy of WestRock's application for exemption renewal is available for review in the docket for this notice.

Terms of the Exemption

Period of the Exemption

The requested exemption is proposed to be effective April 17, 2019, through 11:59 p.m. on April 16, 2024, for drivers employed by WestRock operating CMVs on Compress Street in Chattanooga,

Tennessee, between the company's shipping and receiving departments.

Extent of the Exemption

The exemption would be restricted to drivers employed by WestRock operating CMVs on the route specified above. This exemption would be strictly limited to the provisions of 49 CFR 395.3(a)(1), referring to a required minimum of 10 hours off duty before the start of a duty period, and 395.3(a)(2), commonly referred to as the "14-hour rule." When operationally necessary, drivers would be allowed up to a 16-hour duty period and no fewer than 8 hours off duty prior to the duty period.

Preemption

During the period this exemption would be in effect, no State would be allowed to enforce any law or regulation that conflicted with or was inconsistent with this exemption with respect to a firm or person operating under the exemption (49 U.S.C. 31315(d)).

Notification to FMCSA

WestRock would be required to notify FMCSA within 5 business days of any accident (as defined in 49 CFR 390.5), involving any of the motor carrier's CMVs operating under the terms of this exemption. The notification would be required to include the following information:

- a. Name of the Exemption: "WestRock"
- b. Date of the accident,
- c. City or town, and State, in which the accident occurred, or which is closest to the scene of the accident,
- d. Driver's name and driver's license State, number, and class,
- e. Co-Driver's name and driver's license State, number, and class,
- f. Vehicle company number and power unit license plate State and number,
- g. Number of individuals suffering physical injury,
- h. Number of fatalities,
- i. The police-reported cause of the accident,
- j. Whether the driver was cited for violation of any traffic laws, or motor carrier safety regulations, and
- k. The total driving time and the total on-duty time of the CMV driver at the time of the accident.

Reports filed under this provision would be emailed to MCPSD@DOT.GOV.

Termination

The FMCSA does not believe the drivers covered by this exemption, if granted, would experience any

deterioration of their safety record. However, should this occur, FMCSA would take all steps necessary to protect the public interest, including revocation of the exemption. The FMCSA would immediately revoke the exemption for failure to comply with its terms and conditions.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-02955 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2014-0213; FMCSA-2015-0323]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 12 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have “no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-2014-0213; FMCSA-2015-0323, in the keyword box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

II. Background

On November 20, 2018, FMCSA published a notice announcing its decision to renew exemptions for 12 individuals from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) to operate a CMV in interstate commerce and requested comments from the public (83 FR 56683). The public comment period ended on December 20, 2018, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a

CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 12 renewal exemption applications, FMCSA announces its decision to exempt the following drivers from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8).

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of September and are discussed below. As of September 9, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (83 FR 58683):

Mark D. Anderson (NC)
 Jeremy N. Bradford (AL)
 Jeffrey B. Green (CA)
 Stephen M. Harmon (WV)
 Donald A. Horst (MD)
 Kyle P. Loney (WA)
 Leigh P. Mallory (VT)
 Raymond VanDeMark (NJ)

The drivers were included in docket number FMCSA-2015-0323. Their exemptions are applicable as of September 9, 2018, and will expire on September 9, 2020.

As of September 16, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (83 FR 58683):

Lee H. Anderson (MA)
 Gary A. Combs, Jr. (KY)
 Roland K. Mezger (PA)
 Robert Thomas, Jr. (NC)

The drivers were included in docket number FMCSA-2014-0213. Their exemptions are applicable as of September 16, 2018, and will expire on September 16, 2020.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than

was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-02952 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2001-9800]

Qualifications of Drivers; Exemption Applications; Diabetes; Withdrawal of Notices of Final Disposition

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of withdrawal of 2003 and 2005 final disposition notices for the diabetes exemption program.

SUMMARY: FMCSA withdraws its September 3, 2003, notice concerning exemptions for certain individuals with insulin-treated diabetes mellitus (ITDM) and its November 8, 2005, revision. This action is in response to the Qualifications of Drivers; Diabetes Standard final rule, published on September 19, 2018, which revised the physical qualifications standard for ITDM individuals who wish to operate commercial motor vehicles (CMVs) in interstate commerce. The revised standard allows certified medical examiners, in consultation with the treating clinician, to evaluate and determine whether to grant an ITDM individual a medical examiner's certificate (MEC) to drive a CMV in interstate commerce. FMCSA has determined, therefore, that an exemption program for ITDM individuals is no longer necessary.

DATES: This notice is applicable February 21, 2019.

FOR FURTHER INFORMATION CONTACT: Ms. Christine Hydock, Chief, Medical Programs Division, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, by telephone at (202) 366-4001, or by email at fmcsamedical@dot.gov. If you have questions on viewing material in the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1970, 49 CFR 391.41(b)(3) prohibited ITDM individuals from operating CMVs. On September 3, 2003, FMCSA announced that the Agency would begin authorizing exemptions from 49 CFR 391.41(b)(3) for certain ITDM individuals (68 FR 52441). Section 31315(b)(2) of 49 U.S.C. allows the Agency to grant exemptions for a 2-year period and to renew them at the end of the period.¹ The 2003 notice of final disposition outlined the requirements for ITDM individuals to apply for an exemption, and the considerations FMCSA would apply in determining whether to grant such applications in accordance with the statute and the provisions of 49 CFR part 381, subpart C. It addressed the requirements to renew exemptions and the considerations that would be used by the Agency to determine whether to renew an exemption once issued. It also set out the circumstances that would require revocation of an exemption.

In response to the enactment of section 4129(a) through (c) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59, 119 Stat. 1144, 1742, Aug. 10, 2005), the Agency revised certain considerations for such exemptions on November 8, 2005 (70 FR 67777).

On September 19, 2018, the Agency published a final rule revising the physical qualification standard for operators of CMVs with ITDM (83 FR 47486). As of September 19, 2018, there were 4,719 ITDM drivers who held Federal diabetes exemptions. While the exemption program provides a pathway to medical certification for ITDM individuals who otherwise meet the physical qualifications standards of 49 CFR 391.41(b), the amended diabetes standard provides a less burdensome approach that emphasizes individualized assessment and utilizes the treating clinician of the ITDM individual to assist the certified medical examiner in making the certification determination. Detailed explanations of the process for complying with the new physical qualification requirements are included in the preamble to the final rule published on September 19, 2018.

II. Transition From Exemption Program to the New Standard

The withdrawal of the 2003 and 2005 program notices is applicable February

¹ At the time, the statute limited exemptions to 2 years. The statute was subsequently amended to allow exemptions for up to 5 years, but, as a practical matter, diabetes exemptions have been limited to 2 years.

21, 2019. Individuals could begin the process of obtaining MECs following the new streamlined process on November 19, 2018.

A. Existing Diabetes Exemption Holders

Diabetes exemptions under the program are issued for 2 years, but exemption holders must be medically certified by a certified medical examiner and issued an MEC annually. Any MEC that was obtained under an exemption and was in effect when the final rule became effective on November 19, 2018, will remain in effect until the MEC expires or is replaced by an MEC issued under the new standard. Prior to its expiration, a new MEC must be issued under the new standard to operate a CMV. FMCSA will direct certified medical examiners to cease issuing MECs under the exemption program on or after the date of this withdrawal notice.

Beginning November 19, 2018, exemption holders could begin the process of obtaining certification under the new standard. This requires being evaluated by a treating clinician who must complete an Insulin-Treated Diabetes Mellitus Assessment Form, MCSA-5870, which is available on the Agency's website, and then obtaining a medical certification examination by a certified medical examiner. Existing diabetes exemption holders should have adequate time to comply with the provisions of the final rule before their current MECs expire. Obtaining certification under the new standard should be much less burdensome in terms of both time and resources than the lengthy process of applying for and maintaining an exemption.

B. State Driver Licensing Agencies and Variances

When an ITDM individual obtains an MEC under the new standard, it will not be necessary for the certified medical examiner to indicate on the MEC that certification is made consistent with the terms of an exemption (unless other exemptions are involved) because a diabetes exemption is no longer required to operate a CMV. Therefore, in the case of an ITDM individual holding a commercial driver's license or a commercial learner's permit, it will not be necessary for a State Driver Licensing Agency to receive and post the information about such a medical variance on the individual's Commercial Driver's License Information System (CDLIS) record (see 49 CFR 383.73(o)).

Issued on: February 13, 2019.

Raymond P. Martinez,
Administrator.

[FR Doc. 2019-02967 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2019-0004]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 12 individuals for an exemption from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions will enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA-2019-0004 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

• *Fax:* 1-202-493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., ET,

Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2019-0004), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA-2019-0004, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-2019-0004, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the FMCSRs for a five-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The 12 individuals listed in this notice have requested an exemption from the vision requirement in 49 CFR 391.41(b)(10). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal Meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

In July 1992, the Agency first published the criteria for the Vision Waiver Program, which listed the conditions and reporting standards that CMV drivers approved for participation would need to meet (Qualification of Drivers; Vision Waivers, 57 FR 31458, July 16, 1992). The current Vision Exemption Program was established in 1998, following the enactment of amendments to the statutes governing exemptions made by § 4007 of the Transportation Equity Act for the 21st Century (TEA-21), Public Law 105-178, 112 Stat. 107, 401 (June 9, 1998). Vision exemptions are considered under the

procedures established in 49 CFR part 381 subpart C, on a case-by-case basis upon application by CMV drivers who do not meet the vision standards of 49 CFR 391.41(b)(10).

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past three years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA-1998-3637.

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrated the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., "Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process," Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash

predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used three consecutive years of data, comparing the experiences of drivers in the first two years with their experiences in the final year.

III. Qualifications of Applicants

Gary W. Brockway

Mr. Brockway, 63, has had a retinal vein occlusion in his right eye since 2015. The visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2018, his optometrist stated, "In my opinion, Mr. Brockway has sufficient vision to perform the driving task [sic] required to operate a commercial vehicle." Mr. Brockway reported that he has driven straight trucks for 44 years, accumulating 440,000 miles, and tractor-trailer combinations for 44 years, accumulating 880,000 miles. He holds a Class A CDL from Iowa. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Robert W. Estes

Mr. Estes, 47, has had a chorioretinal scar in his left eye since 1971. The visual acuity in his right eye is 20/20, and in his left eye, counting fingers. Following an examination in 2018, his optometrist stated, "In conclusion of the examination results, in my opinion, Roger Estes has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Estes reported that he has driven straight trucks for 10 years, accumulating 110,000 miles. He holds an operator's license from Missouri. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Gilbert J. Graybill

Mr. Graybill, 41, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2018, his optometrist stated, "In my professional opinion, Mr. Graybill displays sufficient vision function to commercially drive." Mr. Graybill reported that he has driven straight trucks for three years, accumulating 260,000 miles. He holds an operator's license from Oklahoma. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Richard D. Livingston, Jr.

Mr. Livingston, 42, has had amblyopia in his right eye since childhood. The

visual acuity in his right eye is 20/50, and in his left eye, 20/20. Following an examination in 2018, his optometrist stated, "It is my medical opinion that Richard Livingston has the visual acuity skills needed to safely operate a commercial vehicle." Mr. Livingston reported that he has driven straight trucks for 22 years, accumulating 44,000 miles. He holds an operator's license from Wisconsin. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Edgar H. Meraz Gardea

Mr. Meraz Gardea, 37, has had a macular hole in his left eye since 2004. The visual acuity in his right eye is 20/20, and in his left eye, 20/100. Following an examination in 2018, his ophthalmologist stated, "Mr. Meraz has been driving commercial vehicle for many years and has the sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Meraz Gardea reported that he has driven straight trucks for 19 years, accumulating 231,000 miles, and tractor-trailer combinations for 17 years, accumulating 207,740 miles. He holds an operator's license from New Mexico. His driving record for the last three years shows no crashes and one conviction for a moving violation in a CMV: Failure to obey traffic signal or light.

Joshua G. Millican

Mr. Millican, 36, has a prosthetic right eye due to a traumatic incident in childhood. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2018 his optometrist stated, "In my medical opinion, Mr. Mullican [sic] has sufficient vision to perform the driving tasks and requirements needed to operate a commercial vehicle." Mr. Millican reported that he has driven straight trucks for 15 years, accumulating 600,000 miles, and tractor-trailer combinations for ten years, accumulating 750,000 miles. He holds a Class A CDL from Ohio. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Daniel C. Reichert

Mr. Reichert, 41, has a macular scar in his right eye due to a traumatic incident in 1999. The visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2018, his optometrist stated, "I feel that Mr. Reichert is adequate to operate a commercial vehicle with his peripheral vision in the right eye and a normal left

eye.” Mr. Reichert reported that he has driven straight trucks for 14 years, accumulating 112,000 miles, and tractor-trailer combinations for 14 years, accumulating 154,000 miles. He holds a Class AM CDL from Georgia. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Gregory D. Shirah

Mr. Shirah, 53, has had macular degeneration in his right eye since 2015. The visual acuity in his right eye is 20/80, and in his left eye, 20/25. Following an examination in 2018, his optometrist stated, “Mr. Shirah has sufficient vision to operate a commercial vehicle.” Mr. Shirah reported that he has driven straight trucks for seven years, accumulating 350,000 miles, and tractor-trailer combinations for 20 years, accumulating two million miles. He holds a Class A CDL from Alabama. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Balwant Singh

Mr. Singh, 28, has a macular scar in his left eye due to a traumatic incident in 2013. The visual acuity in his right eye is 20/20, and in his left eye, 20/150. Following an examination in 2018, his optometrist stated, “Based on today’s findings, it is my medical opinion that I believe Mr. Balwant Singh has sufficient, stable vision in order to perform all tasks required of him to safely operate a commercial vehicle.” Mr. Singh reported that he has driven straight trucks for six years, accumulating 420,000 miles, and tractor-trailer combinations for six years, accumulating 420,000 miles. He holds a Class A CDL from California. His driving record for the last three years shows no crashes and one conviction for a moving violation in a CMV; driving in an improper lane.

Tristan A. Twito

Mr. Twito, 35 has had chorioretinal scarring in his left eye due to a traumatic incident in childhood. The visual acuity in his right eye is 20/20, and in his left eye, hand motion. Following an examination in 2018, his optometrist stated, “The patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Twito reported that he has driven straight trucks for one year, accumulating 30,000 miles, and tractor-trailer combinations for 12 years, accumulating 1.2 million miles. He holds a Class A CDL from Texas. His driving record for the last three years

shows no crashes and no convictions for moving violations in a CMV.

Michael L. Watters, Sr.

Mr. Watters, 63, has a prosthetic right eye due to a traumatic incident in 2004. The visual acuity in his right eye is no light perception, and in his left eye, 20/30. Following an examination in 2018, his optometrist stated, “Patient Michael Watters . . . has been determined by his optometrist to have sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Watters reported that he has driven straight trucks for four years, accumulating 512,000 miles, and tractor-trailer combinations for eight years, accumulating 1.19 million miles. He holds a Class A CDL from Pennsylvania. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

Dana J. York

Mr. York, 50, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/80. Following an examination in 2018, his optometrist stated, “Patient has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. York reported that he has driven tractor-trailer combinations for 25 years, accumulating 400,000 miles. He holds an operator’s license from Pennsylvania. His driving record for the last three years shows no crashes and no convictions for moving violations in a CMV.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments and material received before the close of business on the closing date indicated in the dates section of the notice.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-02966 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2019–0027]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from six individuals for an exemption from the prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to control a commercial motor vehicle (CMV) to drive in interstate commerce. If granted, the exemptions would enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2019–0027 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions

regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2019-0027), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA-2019-0027, in the keyword box, and click "Search." When the new screen appears, click on the "Comment Now!" button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA-2019-0027, in the keyword box, and click "Search." Next, click the "Open Docket Folder" button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the FMCSRs for a five-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The six individuals listed in this notice have requested an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy: § 391.41(b)(8)*, paragraphs 3, 4, and 5.]

The advisory criteria states the following:

If an individual has had a sudden episode of a non-epileptic seizure or loss of consciousness of unknown cause

that did not require anti-seizure medication, the decision whether that person's condition is likely to cause the loss of consciousness or loss of ability to control a CMV should be made on an individual basis by the Medical Examiner in consultation with the treating physician. Before certification is considered, it is suggested that a six-month waiting period elapse from the time of the episode. Following the waiting period, it is suggested that the individual have a complete neurological examination. If the results of the examination are negative and anti-seizure medication is not required, then the driver may be qualified.

In those individual cases where a driver had a seizure or an episode of loss of consciousness that resulted from a known medical condition (e.g., drug reaction, high temperature, acute infectious disease, dehydration, or acute metabolic disturbance), certification should be deferred until the driver has recovered fully from that condition, has no existing residual complications, and is not taking anti-seizure medication.

Drivers who have a history of epilepsy/seizures, off anti-seizure medication and seizure-free for 10 years, may be qualified to operate a CMV in interstate commerce. Interstate drivers with a history of a single unprovoked seizure may be qualified to drive a CMV in interstate commerce if seizure-free and off anti-seizure medication for a five-year period or more.

As a result of Medical Examiners misinterpreting advisory criteria as regulation, numerous drivers have been prohibited from operating a CMV in interstate commerce based on the fact that they have had one or more seizures and are taking anti-seizure medication, rather than an individual analysis of their circumstances by a qualified Medical Examiner based on the physical qualification standards and medical best practices.

On January 15, 2013, FMCSA announced in a Notice of Final Disposition titled, *Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders*, (78 FR 3069), its decision to grant requests from 22 individuals for exemptions from the regulatory requirement that interstate CMV drivers have "no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV." Since the January 15, 2013 notice, the Agency has published additional notices granting requests from individuals for exemptions from the regulatory requirement regarding epilepsy found in 49 CFR 391.41(b)(8).

¹ See http://www.ecfr.gov/cgi-bin/text-idx?SID=e47b48a9ea42dd67d999246e23d97970&mc=true&node=pt49.5.391&rgn=div5#ap49.5.391_171.a and <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

To be considered for an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8), applicants must meet the criteria in the 2007 recommendations of the Agency's Medical Expert Panel (MEP) (78 FR 3069).

III. Qualifications of Applicants

John D. Archer

Mr. Archer is a 66-year-old class A CDL holder in Missouri. He has a history of a seizure disorder and has been seizure free since 2001. He takes anti-seizure medication with the dosage and frequency remaining the same since 2001. His physician states that he is supportive of Mr. Archer receiving an exemption.

Travis W. Flowers

Mr. Flowers is a 27-year-old class D driver in Virginia. He has a history of epilepsy and has been seizure free since 1997. He takes anti-seizure medication with the dosage and frequency remaining the same since 2016. His physician states that he is supportive of Mr. Flowers receiving an exemption.

Stephen T. Root

Mr. Root is a 46-year-old DM driver in New York. He has a history of epilepsy and has been seizure free since 1996. His anti-seizure medication was discontinued in 2001. His physician states that she is supportive of Mr. Root receiving an exemption.

Jeffrey L. Slagan

Mr. Slagan is a 55-year-old class D driver in Wisconsin. He has a history of epilepsy and has been seizure free since 1985. He takes anti-seizure medication with the dosage and frequency remaining the same since 1985. His physician states that he is supportive of Mr. Slagan receiving an exemption.

Dereck Welch

Mr. Welch is a 59-year-old class E driver in Florida. He has a history of epilepsy and has been seizure free since 2009. He takes anti-seizure medication with the dosage and frequency remaining the same since 2009. His physician states that he is supportive of Mr. Welch receiving an exemption.

Mark D. Wray

Mr. Wray is a 34-year-old class D driver in New York. He has a history of epilepsy and has been seizure free since 2010. He takes anti-seizure medication with the dosage and frequency remaining the same since 2010. His physician states that he is supportive of Mr. Wray receiving an exemption.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the dates section of the notice.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019-02954 Filed 2-20-19; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2000-7006; FMCSA-2000-7165; FMCSA-2000-7363; FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-13411; FMCSA-2004-17984; FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-24015; FMCSA-2006-24783; FMCSA-2006-25246; FMCSA-2006-26066; FMCSA-2008-0174; FMCSA-2008-0266; FMCSA-2008-0292; FMCSA-2008-0340; FMCSA-2009-0291; FMCSA-2010-0114; FMCSA-2010-0201; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2011-0124; FMCSA-2012-0279; FMCSA-2012-0280; FMCSA-2014-0004; FMCSA-2014-0296; FMCSA-2014-0298; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2016-0029; FMCSA-2016-0208]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 61 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirements in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before March 25, 2019.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA-2000-7006; FMCSA-2000-7165; FMCSA-2000-7363; FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-13411; FMCSA-2004-

17984; FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-24015; FMCSA-2006-24783; FMCSA-2006-25246; FMCSA-2006-26066; FMCSA-2008-0174; FMCSA-2008-0266; FMCSA-2008-0292; FMCSA-2008-0340; FMCSA-2009-0291; FMCSA-2010-0114; FMCSA-2010-0201; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2011-0124; FMCSA-2012-0279; FMCSA-2012-0280; FMCSA-2014-0004; FMCSA-2014-0010; FMCSA-2014-0296; FMCSA-2014-0298; FMCSA-2014-0300; FMCSA-2014-0301; FMCSA-2016-0029; FMCSA-2016-0208 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

To avoid duplication, please use only one of these four methods. See the "Public Participation" portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA-2000-7006; FMCSA-2000-7165; FMCSA-2000-7363; FMCSA-2000-7918; FMCSA-2000-8398; FMCSA-2002-13411; FMCSA-2004-17984; FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-24015; FMCSA-2006-24783; FMCSA-2006-25246; FMCSA-2006-26066; FMCSA-2008-0174; FMCSA-2008-0266; FMCSA-2008-0292; FMCSA-2008-0340; FMCSA-2009-

0291; FMCSA–2010–0114; FMCSA–2010–0201; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0124; FMCSA–2012–0279; FMCSA–2012–0280; FMCSA–2014–0004; FMCSA–2014–0010; FMCSA–2014–0296; FMCSA–2014–0298; FMCSA–2014–0300; FMCSA–2014–0301; FMCSA–2016–0029; FMCSA–2016–0208), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, put the docket number, FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–7363; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–13411; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2004–19477; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2008–0174; FMCSA–2008–0266; FMCSA–2008–0292; FMCSA–2008–0340; FMCSA–2009–0291; FMCSA–2010–0114; FMCSA–2010–0201; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0124; FMCSA–2012–0279; FMCSA–2012–0280; FMCSA–2014–0004; FMCSA–2014–0010; FMCSA–2014–0296; FMCSA–2014–0298; FMCSA–2014–0300; FMCSA–2014–0301; FMCSA–2016–0029; FMCSA–2016–0208, in the keyword box, and click “Search.” When the new screen appears, click on the “Comment Now!” button and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as

being available in the docket, go to <http://www.regulations.gov>. Insert the docket number, FMCSA–2000–7006; FMCSA–2000–7165; FMCSA–2000–7363; FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–13411; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2004–19477; FMCSA–2006–24015; FMCSA–2006–24783; FMCSA–2006–25246; FMCSA–2006–26066; FMCSA–2008–0174; FMCSA–2008–0266; FMCSA–2008–0292; FMCSA–2008–0340; FMCSA–2009–0291; FMCSA–2010–0114; FMCSA–2010–0201; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0124; FMCSA–2012–0279; FMCSA–2012–0280; FMCSA–2014–0004; FMCSA–2014–0010; FMCSA–2014–0296; FMCSA–2014–0298; FMCSA–2014–0300; FMCSA–2014–0301; FMCSA–2016–0029; FMCSA–2016–0208, in the keyword box, and click “Search.” Next, click the “Open Docket Folder” button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays.

C. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. 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.

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds that such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver’s medical certification.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40

(Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 61 individuals listed in this notice have requested renewal of their exemptions from the vision standard in 49 CFR 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than five years from its approval date and may be renewed upon application. FMCSA grants exemptions from the vision standard for a two-year period to align with the maximum duration of a driver’s medical certification. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 61 applicants has satisfied the renewal conditions for obtaining an exemption from the vision standard (see 65 FR 20245; 65 FR 33406; 65 FR 45817; 65 FR 57230; 65 FR 66286; 65 FR 77066; 65 FR 78256; 66 FR 13825; 66 FR 16311; 67 FR 57266; 67 FR 71610; 67 FR 76439; 68 FR 10298; 68 FR 10300; 68 FR 13360; 69 FR 33997; 69 FR 53493; 69 FR 61292; 69 FR 62741; 69 FR 64806; 69 FR 64810; 70 FR 2705; 70 FR 7545; 70 FR 7546; 70 FR 12265; 71 FR 14566; 71 FR 30227; 71 FR 32183; 71 FR 41310; 71 FR 55820; 71 FR 62147; 71 FR 63379; 71 FR 63380; 71 FR 66217; 72 FR 180; 72 FR 1050; 72 FR 1051; 72 FR 1056; 72 FR 7111; 72 FR 7812; 72 FR 9397; 72 FR 11426; 73 FR 27014; 73 FR 38497; 73 FR 48271; 73 FR 51689; 73 FR 60398; 73 FR 61922; 73 FR 61925; 73 FR 63047; 73 FR 74563; 73 FR 74565; 73 FR 75803; 73 FR 75806; 73 FR 76439; 73 FR 78423; 74 FR 981; 74 FR 6209; 74 FR 6211; 74 FR 6212; 74 FR 6689; 74 FR 8302; 74 FR 65842; 75 FR 9478; 75 FR 34211; 75 FR

44050; 75 FR 47888; 75 FR 54958; 75 FR 59327; 75 FR 66423; 75 FR 70078; 75 FR 72863; 75 FR 77492; 75 FR 77942; 75 FR 77949; 75 FR 79079; 75 FR 79083; 75 FR 79084; 76 FR 2190; 76 FR 4413; 76 FR 4414; 76 FR 5425; 76 FR 9859; 76 FR 9861; 76 FR 9865; 76 FR 11215; 76 FR 34136; 76 FR 55463; 77 FR 13689; 77 FR 40945; 77 FR 60008; 77 FR 60010; 77 FR 64839; 77 FR 68199; 77 FR 68200; 77 FR 68202; 77 FR 71671; 77 FR 74273; 77 FR 74734; 77 FR 75494; 77 FR 75496; 77 FR 76166; 78 FR 800; 78 FR 8689; 78 FR 10250; 78 FR 11731; 78 FR 12813; 78 FR 12822; 78 FR 14410; 79 FR 14331; 79 FR 18392; 79 FR 29498; 79 FR 40945; 79 FR 51643; 79 FR 58856; 79 FR 59357; 79 FR 64001; 79 FR 65759; 79 FR 65760; 79 FR 68199; 79 FR 69985; 79 FR 72754; 79 FR 73393; 79 FR 73686; 79 FR 73687; 79 FR 74169; 80 FR 603; 80 FR 2473; 80 FR 3723; 80 FR 6162; 80 FR 7678; 80 FR 7679; 80 FR 8751; 80 FR 8927; 80 FR 15859; 80 FR 18693; 80 FR 20562; 81 FR 42054; 81 FR 70253; 81 FR 71173; 81 FR 90050; 81 FR 96165; 81 FR 96180; 81 FR 96191; 82 FR 13043; 82 FR 13048). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of March and are discussed below. As of March 1, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 39 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 20245; 65 FR 33406; 65 FR 57230; 67 FR 57266; 69 FR 33997; 69 FR 53493; 69 FR 61292; 69 FR 62741; 69 FR 64806; 69 FR 64810; 70 FR 2705; 71 FR 32183; 71 FR 41310; 71 FR 55820; 71 FR 62147; 71 FR 63379; 71 FR 63380; 71 FR 66217; 72 FR 180; 72 FR 1050; 72 FR 1051; 72 FR 1056; 72 FR 9397; 73 FR 38497; 73 FR 48271; 73 FR 60398; 73 FR 61922; 73 FR 61925; 73 FR 74563; 73 FR 74565; 73 FR 75803;

73 FR 75806; 73 FR 76439; 73 FR 78423; 74 FR 981; 74 FR 6209; 74 FR 6211; 74 FR 65842; 75 FR 9478; 75 FR 34211; 75 FR 44050; 75 FR 47888; 75 FR 54958; 75 FR 59327; 75 FR 66423; 75 FR 70078; 75 FR 72863; 75 FR 77492; 75 FR 77949; 75 FR 79079; 75 FR 79083; 75 FR 79084; 76 FR 2190; 76 FR 4413; 76 FR 4414; 76 FR 5425; 76 FR 9865; 76 FR 34136; 76 FR 55463; 77 FR 13689; 77 FR 40945; 77 FR 60008; 77 FR 60010; 77 FR 64839; 77 FR 68199; 77 FR 68200; 77 FR 68202; 77 FR 71671; 77 FR 74273; 77 FR 74734; 77 FR 75494; 77 FR 75496; 77 FR 76166; 78 FR 800; 78 FR 11731; 78 FR 12813; 79 FR 14331; 79 FR 18392; 79 FR 29498; 79 FR 40945; 79 FR 51643; 79 FR 58856; 79 FR 59357; 79 FR 64001; 79 FR 65759; 79 FR 65760; 79 FR 68199; 79 FR 69985; 79 FR 72754; 79 FR 73393; 79 FR 73686; 79 FR 73687; 79 FR 74169; 80 FR 603; 80 FR 2473; 80 FR 3723; 80 FR 6162; 80 FR 7678; 80 FR 7679; 80 FR 8751; 80 FR 8927; 80 FR 18693; 81 FR 42054; 81 FR 70253; 81 FR 71173; 81 FR 90050; 81 FR 96165; 81 FR 96180; 81 FR 96191; 82 FR 13043; 82 FR 13048);

Charles H. Akers, Jr. (VA)
Gerald D. Bowser (PA)
William L. Brady (KS)
Donald O. Clopton (AL)
Thomas A. Crowell (NC)
Ivory Davis (MD)
William W.R. Dunn (PA)
Jevont D. Fells (AL)
Barry J. Ferdinando (NH)
Raymundo Flores (TX)
Rici W. Giesseman (OH)
Harlan L. Gunter (VA)
Thomas H. Gysbers (WI)
David M. Hagadorn (NJ)
William J. Hall (WA)
Guadalupe J. Hernandez (IN)
Kenneth Liuzza (LA)
Kenny Y. Louie (CA)
John T. Mabry (FL)
David S. Matheny (WA)
Tom A. McCarty (NM)
Timothy R. McCullough (FL)
Timothy L. Miller (IA)
Norman Mullins (OH)
Neville E. Owens (NC)
Jeffrey S. Pennell (VT)
Leonardo Polonski (MA)
Don C. Powell (NY)
Myriam Rodriguez (CA)
Lynn R. Schraeder (IA)
David W. Skillman (WA)
Randall S. Surber (WV)
Jeffrey L. Tanner (WY)
Ricky L. Watts (FL)
Patricia A. White (IL)
Steven E. Williams (GA)
Olen L. Williams, Jr. (TN)
Michael T. Wimber (MT)
Rick A. Young (IN)

The drivers were included in docket numbers FMCSA-2000-7006; FMCSA-2000-7165; FMCSA-2004-17984;

FMCSA-2004-18885; FMCSA-2004-19477; FMCSA-2006-24783; FMCSA-2006-25246; FMCSA-2006-26066; FMCSA-2008-0174; FMCSA-2008-0292; FMCSA-2008-0340; FMCSA-2009-0291; FMCSA-2010-0114; FMCSA-2010-0201; FMCSA-2010-0354; FMCSA-2010-0385; FMCSA-2011-0124; FMCSA-2012-0279; FMCSA-2012-0280; FMCSA-2014-0004; FMCSA-2014-0010; FMCSA-2014-0296; FMCSA-2014-0298; FMCSA-2014-0300; FMCSA-2016-0029; FMCSA-2016-0208. Their exemptions are applicable as of March 1, 2019, and will expire on March 1, 2021.

As of March 4, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following three individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 45817; 65 FR 77066; 67 FR 71610; 67 FR 76439; 68 FR 10298; 70 FR 7545; 72 FR 7812; 74 FR 6689; 76 FR 9859; 78 FR 8689; 80 FR 7678; 82 FR 13043);

Harry P. Henning (PA); Christopher L. Humphries (TX); and Ralph J. Miles (OR)

The drivers were included in docket numbers FMCSA-2000-7363; FMCSA-2002-13411. Their exemptions are applicable as of March 4, 2019, and will expire on March 4, 2021.

As of March 7, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following nine individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 66286; 66 FR 13825; 68 FR 10300; 70 FR 7546; 72 FR 7111; 74 FR 6212; 76 FR 9861; 78 FR 10250; 80 FR 6162; 80 FR 7679; 80 FR 20562; 82 FR 13043);

Jason P. Atwater (UT)
Steven D. Ellsworth (IL)
Abdalla M. Jalili (IL)
Alan L. Johnston (IL)
Richard A. Pierce (MO)
Rance A. Powell (AL)
Richard P. Rebel (ND)
Mustafa Shahadeh (OH)
Charles P. Smith (MO)

The drivers were included in docket numbers FMCSA-2000-7918; FMCSA-2014-0301. Their exemptions are applicable as of March 7, 2019, and will expire on March 7, 2021.

As of March 23, 2019, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 66286; 65

FR 78256; 66 FR 13825; 66 FR 16311; 67 FR 76439; 68 FR 10298; 68 FR 13360; 70 FR 7545; 70 FR 12265; 71 FR 14566; 71 FR 30227; 72 FR 7812; 72 FR 11426; 73 FR 27014; 73 FR 51689; 73 FR 63047; 73 FR 75803; 74 FR 6209; 74 FR 6689; 74 FR 8302; 75 FR 77942; 75 FR 77949; 76 FR 4413; 76 FR 5425; 76 FR 9859; 76 FR 9861; 76 FR 11215; 78 FR 8689; 78 FR 12822; 78 FR 14410; 80 FR 15859; 82 FR 13043);

Howard K. Bradley (VA)
Willie Burnett, Jr. (FL)
Marcus L. Conner (TX)
Thomas G. Danclovic (MO)
Donald K. Driscoll (MA)
William G. Holland (AR)
Thomas F. Marczewski (WI)
Steve A. Reece (TN)
Jeremichael Steele (NC)
Wade D. Taylor (MO)

The drivers were included in docket numbers FMCSA–2000–7918; FMCSA–2000–8398; FMCSA–2002–13411; FMCSA–2006–24015; FMCSA–2008–0266; FMCSA–2008–0340; FMCSA–2010–0385. Their exemptions are applicable as of March 23, 2019, and will expire on March 23, 2021.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified Medical Examiner, as defined by 49 CFR 390.5, who attests that the driver is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file or keep a copy of his/her driver's qualification if he/her is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 61 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above. In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: February 13, 2019.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2019–02965 Filed 2–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0141]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From Stoneridge, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant Stoneridge, Inc.'s (Stoneridge) application for a limited 5-year exemption to allow motor carriers to operate commercial motor vehicles (CMV) with the company's MirrorEye™ Camera Monitor System (CMS) installed as an alternative to the two rear-vision mirrors required by the Federal Motor Carrier Safety Regulations (FMCSR). The Agency has determined that granting the exemption to allow use of the MirrorEye™ system in lieu of mirrors would likely achieve a level of safety equivalent to or greater than the level of safety provided by the regulation.

DATES: This exemption is effective February 21, 2019 and ending February 13, 2024.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–0676, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Docket: For access to the docket to read background documents or comments submitted to notice requesting public comments on the exemption application, go to www.regulations.gov at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line Federal document management system is available 24 hours each day, 365 days each year. The docket number is listed at the beginning of this notice.

SUPPLEMENTARY INFORMATION:

Background

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the FMCSRs. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

Stoneridge Application for Exemption

Stoneridge applied for an exemption from 49 CFR 393.80(a) to allow its MirrorEye™ CMS to be installed as an alternative to the two rear-vision mirrors required on CMVs. A copy of the application is included in the docket referenced at the beginning of this notice.

Section 393.80(a) of the FMCSRs requires that each bus, truck, and truck-tractor be equipped with two rear-vision mirrors, one at each side. The mirrors must be positioned to reflect to the driver a view of the highway to the rear, and the area along both sides of the CMV. Section 393.80(a) cross-references

the National Highway Traffic Safety Administration's (NHTSA) standard for mirrors on motor vehicles, Federal Motor Vehicle Safety Standard (FMVSS) No. 111. Paragraph S7.1 of FMVSS No. 111 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a gross vehicle weight rating (GVWR) greater than 4,536 kg and less than 11,340 kg and each bus, other than a school bus, with a GVWR of more than 4,536 kg. Paragraph S8.1 provides requirements for mirrors on multipurpose passenger vehicles and trucks with a GVWR of 11,340 kg or more.

The MirrorEye™ CMS consists of multiple digital cameras mounted on the exterior of the CMV and enclosed in an aerodynamic package that provides both environmental protection for the cameras and a mounting location for optimal visibility. Each camera has video processing software that presents a clear, high-definition image to the driver by means of a monitor mounted to each A-pillar of the CMV, *i.e.*, the structural member between the windshield and door of the cab. The company explains that attaching the monitors to the A-pillars avoids the creation of incremental blind spots while eliminating the blind spots associated with conventional mirrors. Stoneridge states that its CMS meets or exceeds the visibility requirements provided in FMVSS No. 111 based on several factors:

- *Greater field of view (FOV) than conventional mirrors*—Mirrors are replaced by wide angle, narrow angle and look-down cameras expanding the FOV by an estimated 25 percent.
- *Fail-safe design*—The CMS has independent video processing of multiple camera images so that in the unlikely event of an individual camera failure, the other camera images continue to be displayed. This ensures that real-time images are continuously displayed without interruption.
- *Augmented and enhanced vision quality*—The use of high-definition digital cameras provides for color night vision, low light sensitivity and trailer panning capabilities. This assists with night driving, operating under other low lighting conditions, and provides for glare reduction.
- *Trailer panning*—The CMS automatically tracks the end of the trailer to keep it in view while the vehicle is moving forward. Stoneridge believes this feature could eliminate collisions associated with the CMV driver making a right-hand turn, and incidents where the CMV strikes a pedestrian or bicyclist while making right hand turns.

Stoneridge also believes use of its CMS may help to reduce driver fatigue by requiring less head movement by drivers compared to the number of head movement needed to use conventional mirrors. The company claims that use of its CMS provides improved fuel economy because the housing for the system is more aerodynamic than the conventional mirrors required by § 393.80(a).

The exemption would apply to all CMV operators driving vehicles with the MirrorEye™ CMS. Stoneridge believes that mounting the system as described would maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

Comments

FMCSA published a notice of the application in the **Federal Register** on April 5, 2018, and asked for public comment (83 FR 14716). The Agency received 31 comments from: The American Trucking Associations (ATA); two motor carriers (Schneider National, Inc. (Schneider) and J.B. Hunt Transport Services, Inc. (J.B. Hunt)); the Trucking Alliance; the Commercial Vehicle Safety Alliance (CVSA); Advocates for Highway and Auto Safety (Advocates); and 25 individuals.

ATA supports granting the application to allow use of the CMS as an alternative to the two rear-view mirrors required by the FMCSRs. ATA stated "Granting this and similar petitions for exemption from FMCSR 393.80 requirements that currently are barriers to mirrorless technology will provide valuable real-world experience and data to inform future regulatory action to allow CMS technology as an alternative to rear view mirrors for all vehicle types."

Further, ATA stated:

. . . motor carriers and truck manufacturers recognize the potential of CMS for improving both safe operations and fuel efficiency when compared with traditional exterior mirrors. For example, CMS can provide the following functions beyond what traditional mirrors offer: Trailer swing video panning view capabilities; wider viewing angles of driver blind spots encompassing multiple mirror locations (*i.e.*, hood spot mirrors) to one vantage point; direct solar glare resistance, and night vision capabilities. It should also be noted that CMS can be designed and placed in a way that reduces the chances of damage compared with traditional mirrors, which can improve vehicle uptime and reduce maintenance and operational costs by eliminating traditional mirror repair/replacement and allowing faster driver pre/post trip inspections and technician/officer inspections.

Schneider and J.B. Hunt stated that they have been using the MirrorEye™ CMS, in addition to the required mirrors, in a select number of vehicles, and both motor carriers support granting Stoneridge's application. Schneider states that its drivers using the MirrorEye™ CMS have (1) "had an overwhelmingly positive experience," and (2) confirmed some of the benefits touted by Stoneridge in its application, including improved visibility in night driving and low light conditions, improved visibility due to auto tracking of the trailer, and reduced driver distraction due to light and glare reduction. J.B. Hunt states that "we have not been involved in any collisions and have received overwhelming positive feedback from our test drivers." J. B. Hunt also states that its drivers noted benefits such as "real time, excellent monitor image clarity with improved field of vision around their tractor and trailing units and elimination of the tractor's problematic front passenger side blind spot."

The Trucking Alliance, a coalition of freight and logistics companies that are working together to increase safety for commercial truck drivers, reduce the number of large truck accidents, and improve highway safety for the general public throughout the United States, also supports granting the Stoneridge application. The Trucking Alliance notes that some of its member carriers have been testing the technologies offered by Stoneridge that are the subject of the exemption application. The Trucking Alliance states:

Carriers report that this Stoneridge technology is performing at better than acceptable levels of performance. Carriers have reported no collisions. Drivers report that the technology works and benefits them in eliminating many of the problems associated with conventional side mirrors. For example, one Trucking Alliance member carrier has reported driver feedback includes such observations as a 'greater field of vision, color night vision images, and the trailer panning feature which tracks the end of the trailer during turning and backing maneuvers.'

Thirteen individuals commented in support of granting the temporary exemption, and noted various advantages of the Stoneridge CMS as compared to the rear vision mirrors required by the FMCSRs including (1) economic benefits related to fuel economy gains and carbon emission reductions from reduced drag forces, (2) superior total field-of-view around a CMV, including reduction/elimination of blind spots (3) increased visibility when driving at night and during inclement weather, (4) enhanced vehicle

maneuverability in backing, turning, and lane changes through use of trailer scanning, (5) and reduced driver fatigue.

CVSA stated that while it recognizes there may be potential safety benefits of the proposed technology, it does not have data to support or refute the efficacy of CMS technology. However, CVSA noted that its associate member companies that have some experience with the Stoneridge technology reported that “drivers responded favorably when testing the MirrorEye™ technology and preferred them in place of traditional side mirrors.” Additionally, CVSA noted that granting the exemption may have impacts on roadside enforcement personnel, as inspectors use the mirrors for purposes beyond the intent of the FMVSS and the FMCSRs. Specifically, CVSA states that roadside inspectors use the mirrors to see what is happening inside the cab, and to identify when CMV drivers are operating a vehicle in an unsafe manner, such as illegally using a handheld electronic device, or not wearing a safety belt. Additionally, roadside inspectors frequently use mirrors to visually communicate with drivers during roadside inspections, when at the side or rear of the inspection vehicle. CVSA stated that it is unclear whether the technology has a proven safety benefit, and noted concern that exemptions from safety regulations have the potential to undermine consistency and uniformity in compliance enforcement, and encouraged FMCSA to consider the roadside enforcement and inspection aspects of rear vision mirror usage in the evaluation of the application.

Advocates opposes the Stoneridge application “on the basis that the application is overly broad. The regulations governing requests for exemption requires applications to include ‘an estimate of the number of drivers and commercial motor vehicles (CMVs) that would be operated under the terms and conditions of the exemption’, which in this case could encompass every CMV and driver presently on the U.S. roads. . . we must oppose such an overly broad exemption which would apply for at least five years.” While Advocates opposes the application, it recognized the potential benefits of the technology, and instead urged NHTSA and FMCSA “to establish a pilot program study the benefits of using cameras to enhance commercial vehicle driver visibility as this technology has the potential to reduce or eliminate the large and dangerous blind zones around CMVs.” Advocates states that the rear-vision mirror regulations are, by definition, minimum safety standards, and any exemption

granted by FMCSA “could deny both the driver(s) and the public the minimum required safety protections intended under the FMCSRs and, in this case, the pertinent FMVSS as well.”

Twelve individuals commented opposing the application. Many of these commenters cited concerns regarding the ability of the CMS system to function properly in the event of a system failure (*i.e.*, an electronic malfunction). These commenters also noted concerns about road debris creating partial or complete obstruction of the camera, sunlight and glare on monitor screens causing them to be not visible, and the possibility of increased driver distraction. Some commenters recommended that the CMS system could be used as a secondary, backup system, but that the rear-vision mirrors required by the FMCSRs should be retained in addition to the camera system.

FMCSA Decision

The FMCSA has evaluated the Stoneridge exemption application, and the comments received. For the reasons discussed below, FMCSA believes that granting the exemption to allow motor carriers to operate CMVs with the Stoneridge MirrorEye™ CMS installed as an alternative to the two rear-vision mirrors required by the FMCSRs is likely to achieve a level of safety equivalent to or greater than the level of safety provided by the regulation.

Use of the MirrorEye™ CMS provides CMV drivers with an enhanced field of view when compared to the required rear-vision mirrors because (1) it eliminates the blind spots on both sides of the vehicle created by the required rear-vision mirrors, (2) the multi-camera system expands the field of view compared to the required rear-vision mirrors by an estimated 25 percent, and (3) the trailer panning feature automatically tracks the end of the trailer to keep it in view in forward motion. Additionally, the MirrorEye™ CMS uses high definition cameras and monitors that include features such as color night vision, low light sensitivity, and light and glare reduction that together help provide drivers with improved vision in the field of view when compared to traditional rear-vision mirrors. The MirrorEye™ CMS includes features such as self-cleaning lenses/cameras to eliminate problems with rain and dirt, a feature that is not required for traditional rear-vision mirrors, and an advanced defrosting system for winter driving.

In response to commenters’ concerns about the possibility of electronic malfunctions that may compromise

operation of the system, Stoneridge notes in its application:

The MirrorEye™ CMS is a fail-safe operating system by design due to its independent video processing of multiple camera images. In the unlikely event of an individual camera failure, the other camera images continue to be displayed. Proprietary software ensures that real-time images are continuously displayed without interruption. In addition to the MirrorEye™ CMS multi-camera redundant design, mounting the camera housing high on the vehicle and providing both a power-fold and breakaway feature further reduces the potential damage that is possible in normal operating environments.

Importantly, neither of the motor carriers that provided comments and that are currently using the MirrorEye™ CMS cited any concerns or problems with system functionality.

In response to concerns about the possibility of increased driver distraction, FMCSA notes that the monitors will be located over the A-pillars to maintain the same approximate direction of glance as conventional mirrors, minimizing any possible concerns about increased distraction. And, as Stoneridge notes in its application, the monitor’s mounting location “requires less lateral head movement resulting in an ergonomic benefit and less driver fatigue.”

FMCSA acknowledges Advocates’ concerns about the possible breadth of the exemption if granted. However, part 381 of the FMCSRs does not impose any specific limitations on the number of vehicles that may be covered by a temporary exemption; rather, it requires FMCSA to make a determination that any exemption that is granted is likely to maintain a level of safety that is equivalent to or greater than the level of safety that would be obtained by complying with the regulation. FMCSA believes that the Stoneridge MirrorEye™ CMS meets this burden.

FMCSA also acknowledges CVSA’s concerns regarding the inability of roadside inspectors and law enforcement officers to use rear-vision mirrors for the other uses described in its comments if the exemption is granted to permit use of the MirrorEye™ CMS in lieu of the mirrors. However, use of the rear-vision mirrors for purposes other than driver visibility is beyond the scope of the FMCSR requirements. FMCSA notes that inspectors may still communicate with drivers by means of hand signals/gestures if the system is on, and the driver will continue to see everything that would have been in view with the mirrors.

The FMCSRs impose several operational controls that will help

ensure that the MirrorEye™ CMS is functioning properly at all times. Section 396.7 of the FMCSRs, “Unsafe operations forbidden,” prohibits any vehicle from being operated in such a condition as to likely cause an accident or breakdown of the vehicle. Section 392.7(a) requires each CMV driver to satisfy himself/herself that a vehicle is in safe condition before operating the vehicle, which would include ensuring that the rear-vision mirrors (or in this case, the MirrorEye™ CMS)—are in good working order. Similarly, section 396.13(a) of the FMCSRs requires that, before driving a vehicle, a driver must be satisfied that the vehicle is in safe operating condition. If the MirrorEye™ CMS (effectively functioning as the rear vision mirrors) fails during operation, the driver must complete a driver vehicle inspection report at the completion of the work day as required by section 396.11 of the FMCSRs, and the motor carrier must ensure that the defect is corrected.

Terms and Conditions for the Exemption

The Agency hereby grants the exemption for a 5-year period, beginning February 21, 2019 and ending February 13, 2024. During the temporary exemption period, motor carriers operating CMVs may utilize the Stoneridge MirrorEye™ CMS installed in lieu of the two rear-vision mirrors required by section 393.80 of the FMCSRs. FMCSA emphasizes that this exemption is limited to the Stoneridge MirrorEye™ CMS, and does not apply to any other camera-based mirror replacement system/technology. Section 396.7 of the FMCSRs, “Unsafe operations forbidden,” prohibits any vehicle from being operated in such a condition as to likely cause an accident or a breakdown of the vehicle. If the camera or monitor system fails during normal vehicle operation on the highway, continued operation of the vehicle shall be forbidden until (1) the MirrorEye™ CMS can be repaired, or (2) conventional rear-vision mirrors that are compliant with section 393.80 are installed on the vehicle.

The exemption will be valid for 5 years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) Motor carriers and/or CMVs fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Interested parties possessing information that would demonstrate that motor carriers operating commercial motor vehicles utilizing the Stoneridge MirrorEye™ CMS installed as an alternative to the two rear-vision mirrors required by section 393.80 of the FMCSRs are not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

Preemption

In accordance with 49 U.S.C. 31313(d), as implemented by 49 CFR 381.600, during the period this exemption is in effect, no State shall enforce any law or regulation applicable to interstate commerce that conflicts with or is inconsistent with this exemption with respect to a firm or person operating under the exemption. States may, but are not required to, adopt the same exemption with respect to operations in intrastate commerce.

Issued on: February 13, 2019.

Raymond P. Martinez,
Administrator.

[FR Doc. 2019–02953 Filed 2–20–19; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Interest Rate Paid on Cash Deposited To Secure U.S. Immigration and Customs Enforcement Immigration Bonds

AGENCY: Departmental Offices, Treasury.
ACTION: Notice.

SUMMARY: For the period beginning January 1, 2019, and ending on March 31, 2019, the U.S. Immigration and Customs Enforcement Immigration Bond interest rate is 2.38 per centum per annum.

DATES: Rates are applicable January 1, 2019 to March 31, 2019.

ADDRESSES: Comments or inquiries may be mailed to Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328.

You can download this notice at the following internet addresses: <http://www.treasury.gov> or <http://www.federalregister.gov>.

FOR FURTHER INFORMATION CONTACT:

Ryan Hanna, Manager, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Service, Parkersburg, West Virginia 26106–1328 (304) 480–5120; Will Walcutt, Supervisor, Funds Management Branch, Funds Management Division, Fiscal Accounting, Bureau of the Fiscal Services, Parkersburg, West Virginia 26106–1328, (304) 480–5117.

SUPPLEMENTARY INFORMATION: Federal law requires that interest payments on cash deposited to secure immigration bonds shall be “at a rate determined by the Secretary of the Treasury, except that in no case shall the interest rate exceed 3 per centum per annum.” 8 U.S.C. 1363(a). Related Federal regulations state that “Interest on cash deposited to secure immigration bonds will be at the rate as determined by the Secretary of the Treasury, but in no case will exceed 3 per centum per annum or be less than zero.” 8 CFR 293.2. Treasury has determined that interest on the bonds will vary quarterly and will accrue during each calendar quarter at a rate equal to the lesser of the average of the bond equivalent rates on 91-day Treasury bills auctioned during the preceding calendar quarter, or 3 per centum per annum, but in no case less than zero. [FR Doc. 2015–18545] In addition to this Notice, Treasury posts the current quarterly rate in Table 2b—Interest Rates for Specific Legislation on the TreasuryDirect website.

Gary Grippo,

Deputy Assistant Secretary for Public Finance.

[FR Doc. 2019–02853 Filed 2–20–19; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Social Impact Partnerships To Pay for Results Act Demonstration Projects

AGENCY: Office of Economic Policy, Treasury.

ACTION: Notice of funding availability.

SUMMARY: The Department of the Treasury (Treasury) is issuing this Notice of Funding Availability (NOFA) to invite applications from State and local governments for awards under the Social Impact Partnerships to Pay for Results Act (SIPPRA).¹ An award recipient will receive payment if a specified outcome of the social impact partnership project is achieved, as

¹ Public Law 115–123, Division E, Title VIII, 132 Stat. 269, 42 U.S.C. 1397n–1397n–13.

determined by the project's independent evaluator. The payment to the grantee cannot exceed the value of the outcome to the federal government. Awards made under this NOFA will be administered by Treasury or by another federal agency with expertise in the area of social benefit addressed in the proposed project. Treasury expects to award up to \$66,290,000 in such competitive project grants under this NOFA. In addition, State and local governments receiving project grants will be eligible to receive up to 15 percent of the project grant to pay for all or a portion of the cost of a statutorily required independent evaluator, which will be paid to conduct an independent evaluation regardless of whether outcomes have been met. Treasury expects up to approximately \$9,940,000 to be available to pay for the costs of independent evaluators under this NOFA.

Funding Opportunity Number: UST-SIPPRA-2019-001.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.017.

DATES: Applications under this NOFA must be submitted no earlier than April 22, 2019 and no later than 4:00 p.m. Eastern Time May 22, 2019 electronically via www.Grants.gov.

Treasury will not download and receive such applications until after the application deadline. As discussed in Section D.2.a, Notice of Intent to Apply, Treasury encourages all potential applicants to submit a notice of intent to apply on or prior to April 8, 2019.

For More Information: Questions about this announcement may be directed to William Girardo, SIPPRA Coordinator, at (202) 622-0262 or SIPPRA@Treasury.gov. For complete application and submission information, including online application instructions, please refer to Section D of this NOFA.

A. Funding Opportunity Description

1. Program Purpose

In 2018 Congress appropriated \$100 million to Treasury to implement SIPPRA, which established a new grant demonstration program to encourage funding social programs that achieve results. Under this NOFA, Treasury announces the availability of up to \$66,290,000 for payments for successful outcomes of social impact partnership projects through grants to State and local governments, and, for project evaluations, the availability of up to approximately \$9,940,000. All awards provided through this NOFA are subject to funding availability.

As stated in SIPPRA, the purposes of SIPPRA are

(1) To improve the lives of families and individuals in need;

(2) To redirect funds away from programs that, based on objective data, are ineffective, and into programs that achieve demonstrable, measurable results;

(3) To ensure federal funds are used effectively on social services to produce positive outcomes for both service recipients and taxpayers;

(4) To establish the use of social impact partnerships to address some of the Nation's most pressing problems;

(5) To facilitate the creation of public-private partnerships that bundle philanthropic or other private resources with existing public spending to scale up effective social interventions already being implemented;

(6) To bring pay for performance to the social sector, allowing the United States to improve the impact and effectiveness of vital social services programs while redirecting inefficient or duplicative spending; and

(7) To incorporate outcomes measurement and randomized controlled trials or other rigorous methodologies for assessing program impact.²

2. Types of Funding and Funding Availability

SIPPRA provides funds for two types of awards: (1) Social impact partnership project grants, including grants to pay for independent evaluators for such projects and (2) feasibility study grants. This NOFA only relates to funds for social impact partnership project grants and funds for the cost of a grantee's independent evaluator. Treasury will issue a separate NOFA for feasibility study grants, likely later in 2019.

A grantee under this NOFA will receive a disbursement only if the grantee achieves one or more outcomes specified in the award agreement and such outcomes are validated by an independent evaluator. The federal payment to the grantee for each specified outcome will be not more than the value of the outcome to the federal government. Payment for the cost of the independent evaluator will be made regardless of whether outcomes have been met.

Treasury may make awards to all, some, or none of the applicants under this NOFA and may make awards for amounts less than the amounts requested by applicants.

SIPPRA provides that not less than 50 percent of all federal payments made to carry out social impact partnership project agreements shall be used for

initiatives that directly benefit children.³ Treasury is implementing this provision by allocating 50 percent of the \$66,290,000 available under this NOFA for projects that directly benefit children. Treasury will accordingly grant awards for projects that do not directly benefit children only to the extent that potential federal award payments for such projects in the aggregate do not exceed \$33,145,000. As long as the potential payments for award agreements for projects that do not directly benefit children do not exceed \$33,145,000, the amount of potential payments for projects that do not directly benefit children may exceed the amount of potential payments for projects that do benefit children. For purposes of this determination, Treasury is defining "children" as individuals under the age of 18. For purposes of determining whether a project directly benefits children, the children in question must meet this definition at the time their participation in the project begins.

3. Qualifying Outcomes

Applicants must propose to carry out a "social impact partnership project."⁴ To qualify as a social impact partnership project under this NOFA, SIPPRA requires the project to be designed to produce one or more measurable, clearly defined outcomes that result in social benefit and federal, State, or local government savings through one or more of the following:

(1) Increasing work and earnings by individuals in the United States who are unemployed for more than 6 consecutive months;

(2) Increasing employment and earnings of individuals who have attained 16 years of age but not 25 years of age;

(3) Increasing employment among individuals receiving federal disability benefits;

(4) Reducing the dependence of low-income families on federal means-tested benefits;

(5) Improving rates of high school graduation;

(6) Reducing teen and unplanned pregnancies;

(7) Improving birth outcomes and early childhood health and development among low-income families and individuals;

(8) Reducing rates of asthma, diabetes, or other preventable diseases among low-income families and individuals to reduce the utilization of emergency and other high-cost care;

³ See 42 U.S.C. 1397n-2(f).

⁴ See 42 U.S.C. 1397n-1(c), 1397n-12(4).

² See 42 U.S.C. 1397n.

(9) Increasing the proportion of children living in two-parent families;

(10) Reducing incidences and adverse consequences of child abuse and neglect;

(11) Reducing the number of youth in foster care by increasing adoptions, permanent guardianship arrangements, reunifications, or placements with a fit and willing relative, or by avoiding placing children in foster care by ensuring they can be cared for safely in their own homes;

(12) Reducing the number of children and youth in foster care residing in group homes, child care institutions, agency-operated foster homes, or other non-family foster homes, unless it is determined that it is in the interest of the child's long-term health, safety, or psychological well-being to not be placed in a family foster home;

(13) Reducing the number of children returning to foster care;

(14) Reducing recidivism among juvenile offenders, individuals released from prison, or other high-risk populations;

(15) Reducing the rate of homelessness among our most vulnerable populations;

(16) Improving the health and well-being of those with mental, emotional, and behavioral health needs;

(17) Improving the educational outcomes of children with special needs or from low-income families;

(18) Improving the employment and well-being of returning United States military members;⁵

(19) Increasing the financial stability of low-income families;

(20) Increasing the independence and employability of individuals who are physically or mentally disabled; or

(21) Other measurable outcomes defined by the State or local government that result in positive social outcomes and federal savings.⁶

Demonstration projects may propose enhancements or alternative models that would add to or otherwise complement existing federal programs.

4. Framework for Social Impact Partnership Projects

a. The Pay for Results Model

The pay for results model mandated by SIPBRA differs from that of more traditional federal grant programs, in which the federal government generally

⁵ This may include improving the employment and well-being of United States military members as they transition to civilian status either as non-activated members of the National Guard or Reserves or as they become Veterans of the Armed Forces.

⁶ See 42 U.S.C. 1397n-1(b).

agrees to pay in advance for the cost of programs and services regardless of their outcomes. Under the pay for results model (also referred to as the "pay for success" model), instead of paying for specific processes and services, the federal government agrees to make payments only if specific, predetermined, measurable outcomes are achieved within a given timeframe. SIPBRA provides that the federal government's payment for an outcome cannot exceed the value of the outcome to the federal government.

b. Outcome Payments

Under this NOFA, an applicant may propose one or multiple project outcomes and receive separate payments at separate points in time for each outcome achieved, subject to the independent evaluator validating both the outcome and the value of the outcome to the federal government in the independent evaluator's periodic progress reports and the relevant federal agency's approval of the payment. See Section F.5.b and F.5.c on evaluation progress reports and final reports, respectively.

For each outcome, an applicant may elect to receive an outcome payment if a specific outcome has been met, or, alternatively, may propose a tiered outcome payment scheme based on levels of success in achieving the outcome. In either case, however, only a single outcome payment will be made for each outcome; progress payments will not be made. To the extent that the proposed intervention affects multiple outcomes that are not separable, applicants may only receive payment for achieving the set of non-separable outcomes following the independent evaluator validating that the project achieved the outcomes related to the non-separable outcomes.

If an applicant proposes a tiered outcome scheme, it must (1) specify a floor and the range of each outcome for which it proposes a tiered payment and (2) propose a federal payment for each of those outcomes. An applicant may propose a spread of outcomes, but no further payments will be made if the outcome exceeds the proposed maximum outcome. Applicants must propose a floor that represents a significantly improved outcome over current conditions. Payments will be made only to the extent that the value of the outcome to the federal government is at least equal to the amount of the payment.

c. Partnership Structure

In designing and implementing a project producing one or more of the

statutory outcomes listed above, the State or local government as the eligible applicant may work with other entities, referred to as "partners." In addition to the applicant itself, the partnership may include investors, a service provider, which is the entity that delivers the intervention, and an intermediary. An applicant also may fulfill one or more of these roles—for example—it may be the service provider or the intermediary. See Appendix I.2, Other Key Parties, for definitions of each of these terms.

d. Partnership Agreement

The partnership agreement between the applicant and the partners, which must be attached to the grant application, must address each of the following:

- Clearly defined roles and responsibilities of each partner;
- A service delivery plan that is flexible and adaptive to the problem and the target population;
- An evaluation design plan;
- A plan for sharing data among the partners, including but not limited to a Memorandum of Understanding or Memorandum of Agreement, which may be conditioned on award of a grant, that appropriately safeguards the privacy of individuals in the targeted population in accordance with applicable laws;
- A representation that all project partners have reviewed an independent evaluation plan for the project and an agreement by all the partners to cooperate in the implementation of the evaluation plan as necessary; and
- A payment arrangement between the applicant and project partners (including the intermediary and/or investors, as applicable), demonstrating that all partners understand that payment by the federal government is conditioned upon the independent evaluator's verification that the project's predetermined outcome(s) and value generated have been met within the grant period.

This payment arrangement must include a plan and timeline describing each payment point that the project partners have agreed on, and the corresponding outcome targets that will be evaluated in the impact evaluation. Although the federal government generally will make payments to the grantee if the independent evaluator determines that the project achieved the specified outcome as a result of the intervention and the payment is less than or equal to the value of the outcome to the federal government,⁷ it

⁷ See 42 U.S.C. 1397n-2(c)(1)(B) and (2).

is not responsible for making payments to the grantee's partners.

e. Independent Evaluator

The applicant also must contract with an independent evaluator, whose responsibilities include assessing whether the project has achieved the outcomes on which payment by the federal government are conditioned. As part of the evaluation, the independent evaluator must also provide an analysis of the observed federal budgetary impact, which the federal government will use to determine whether outcome payment(s) will be made, and, if so, the amount of the payment(s). See Section A.5, Independent Evaluations. The applicant must avoid the selection of an independent evaluator whose objectivity might be impaired. Payment for the evaluation must not be tied in any way to the achievement of the outcomes, and the independent evaluator must not have a financial or other stake in the project that would undermine its objectivity.

5. Outcomes

An outcome is a positive impact on a target population that an applicant expects to achieve as a result of an intervention over the duration of a project. An outcome is measured by one or more indicators that are specific, unambiguous, and observable during the intervention period. Well-defined, achievable, and measurable outcomes form the foundation of the pay for results concept. Whether suitable outcome targets (also referred to as outcome goals) can be identified and agreed upon by the partnership is a key determinant of whether pay for results is the appropriate instrument for addressing the identified social issue.

To qualify for an outcome payment, a project must meet one or more positive outcomes that will result in value to the federal government.⁸ Applicants must describe how specific outcomes will be measured and provide rigorous evidence demonstrating that the intervention can be expected to produce these outcomes.⁹

a. Outcome Target

An outcome target is a change in an outcome measure or a percentage improvement of the outcome measure over the duration of a project and must be defined relative to the comparison or control group (the baseline). Each outcome measure applicants propose should (1) be observable, (2) able to be defined, as a function of the data

applicants intend to use so units of measurement are clearly defined, and, (3) using historical data, show that the proposed outcome target is an improvement over the current status of the target population. Applicants must outline the data and metrics that will be used in measuring outcomes and must also explain how the independent evaluator will gain access to or collect the necessary data. The improvement over the current status must be the result of the intervention and not produced due to random chance, general economic conditions, other pre-existing conditions or trends, or other causes.

b. Outcome Valuation

The outcome valuation is the public benefit resulting from achieving the outcome target(s), including public sector savings (defined as reduction in outlay costs) and changes in federal tax receipts. The federal payment to the State or local government for each specified outcome achieved as a result of the intervention must be less than or equal to the value of the outcome to the federal government over a period not exceeding the intervention period.¹⁰ For the purposes of determining the value to the federal government, applicants must use a budget impact analysis methodology to estimate the annual and cumulative net effect of each intervention on federal revenues and outlays overall, per dollar of intervention, and per participant over the intervention period. This analysis involves estimating baseline federal revenues and outlays for the target population and then estimating the changes in federal revenues and outlays as a result of each intervention. Estimated changes in federal revenue and outlays must be the direct result of the SIPPR intervention, *i.e.*, the SIPPR intervention must have caused the change in outcome that affected federal revenue and outlays. The outcome valuation should include increases in costs due to intended or unintended impacts of the intervention.

In preparing the estimates, as part of the overall evaluation strategy, applicants must document and submit their estimates of baseline federal revenues and outlays and estimated changes to federal revenues and outlays as a direct result of each proposed intervention such that these estimates are easily replicable. The application must provide sufficient information, *e.g.*, all data sources, such as related literature, assumptions, and justifications, to show how the

applicant arrived at the estimate of the baseline federal revenues and outlays, and changes in federal revenues and outlays as a direct result of the proposed intervention.

Using this methodology, applicants will need to estimate the value to the federal government of the proposed intervention(s) before the intervention(s) take place. The estimate must be submitted as part of the application and will be the applicant's baseline for the intervention. Using the same methodology, independent evaluators will assess the value of the intervention(s) to the federal government after the intervention has taken place.

The following shows the steps involved in calculating the outcome value:

Step 1: Estimate target population baseline over the intervention period under current law (before intervention performed)

A. Estimate total amount of federal revenue paid by target population in dollars, if applicable.

B. Estimate total amount of federal outlays expended on target population, in dollars (includes cost of all federal programs used by target population).

*Step 2: Estimate outcomes and federal outlays and revenues over the intervention period under current law (as of the date this NOFA is published in the **Federal Register**) assuming intervention takes place*

The estimate of value will be limited to the intervention period only and may not be extrapolated beyond the intervention period (which is not to exceed seven years).

C. Estimate total federal taxes paid by target population after its outcomes have changed as a direct result of the SIPPR intervention.

D. Estimate total amount of federal outlays expended on the target population after its outcomes have changed as a direct result of the SIPPR intervention. Applicants should carefully consider how the intervention may cause the substitution of federal benefits delivered through one social program for another. Specifically, applicants should carefully consider how the intervention will affect eligibility for other federal programs and how this will affect the change in federal outlays.

Any changes in federal revenue or spending must flow through the changes in outcomes caused by the SIPPR intervention; these changes must be attributed only to the SIPPR intervention and not to other causes. As explained below, randomized controlled trials (RCT) or quasi-experimental

⁸ See 42 U.S.C. 1397n-2(c).

⁹ See 42 U.S.C. 1397n-1(c)(3), (20).

¹⁰ See 42 U.S.C. 1397n-2(c)(1)(B).

designs are to be used to determine causation.

Step 3: Estimate total value of intervention to the federal government in dollars

Value = change in revenue – change in spending = (c – a) – (d – b)

In accordance with SIPBRA, the federal government will pay no more than the value estimated in Step 3.

The estimates of baseline federal outlays and revenues and the estimated federal outlays and revenues after the intervention should be rounded to the nearest hundred, rounding up any number that ends in a number greater than \$50 to the nearest \$100.

Applicants proposing or generating value to the federal government only through reductions in federal administrative expenses will not be considered eligible to receive outcome payments.

As part of the overall evaluation strategy, applicants must document and submit their estimates of baseline federal revenues and outlays and estimated changes to federal revenues and outlays as a direct result of each proposed intervention such that these analyses can be replicated.¹¹ Specifically, the application must describe all data sources, such as related literature, assumptions, and justifications, used to arrive at the estimates of the changes in federal revenues and outlays as a direct result of the proposed intervention.

In estimating the effect on federal revenues and outlays, applicants should carefully consider the funding structure of the program and whether or not the program is oversubscribed, *i.e.*, the program has more eligible individuals than funding available for services, such that when one individual is removed from the program another eligible individual replaces him or her.¹²

6. Independent Evaluations

This section gives an overview of the following: The role of post-award independent evaluation, independent evaluator qualifications, outcomes definitions and measurement, impact evaluation designs and methodology, and outcome valuation.

¹¹ A tool to assist grantees in their calculations will be available on Treasury's SIPBRA website.

¹² Examples of budget impact analysis may be found in appendices of Congressional Budget Office publications. *See, e.g.*, The Effects of Potential Cuts in SNAP Spending on Households With Different Amounts of Income (2015), <https://www.cbo.gov/publication/49978>; Possible Higher Spending Paths for Veterans' Benefits (2018), <https://www.cbo.gov/publication/44995>. An additional reference to calculate federal outlays and revenues are available from the National Bureau of Economic Research TAXSIM at <http://users.nber.org/~taxsim/>.

a. Overview

Pay for Results evaluations must be conducted by independent evaluators. Grantees can expect to commit significant time and resources to the formal evaluations of their project. All grantees are eligible to receive evaluation funding to help support post-award evaluation costs, regardless of whether outcomes are met. In each case, the federal government will fund only up to 15 percent of the amount of the project award for an independent evaluation of the project. The federal government will base its maximum award of funds for the grantee's cost of an independent evaluator on the amount of the top tier outcome payment. The federal government will fund only completed post-award evaluation work; it will not pay for the portion of an evaluator's contract contemplating evaluation work that is not completed in the event a project terminates earlier than expected.

b. Evaluation Design Plan

Evaluations must meet evidence standards for high quality experimental or non-experimental research to receive agreed-upon outcome payments. (See the definitions of "randomized controlled trial" and "quasi-experimental design" in Appendix I.3, Key Concepts and Other Terms.) Evaluations must use the most appropriate and rigorous research method suitable for the project to estimate impacts. RCTs are preferred to the extent their use is consistent with federal, state and local laws; quasi-experimental designs will be accepted if experimental designs are infeasible. An applicant not using a RCT should explain why a RCT is not appropriate for the particular project. Program models that have a moderate or strong existing base of evidence for their effectiveness are strong candidates for pay for results projects. See Section A.6.e, Evidence Standards, for more information on bases of evidence.

The evaluation design plan must:

1. Describe the existing base of evidence and cite available research literature;
2. Explain how the project is suitable for the proposed evaluation;
3. Describe an approach for coordinating all partners and required evaluation activities, including assisting the independent evaluator in collecting and accessing the necessary data, and include a timeline;
4. Document the project evaluation's research question(s), the data to be collected and analyzed, how data quality and integrity will be maintained,

e.g., how attrition will be minimized, and specify overall and subgroup samples;

5. Describe how the project will be implemented with fidelity, *e.g.*, how random assignment to treatment and control groups will be ensured;

6. Describe the metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of the intervention, *i.e.*, key outcomes and outcome targets; an explanation of how the metrics will be measured; and an explanation of how the metrics are independent, objective indicators of impact and are not subject to manipulation by the service provider, the intermediary, or investors, if any;

7. Explain how the independent evaluator will collect or gain access to the metrics that will be used;

8. Explain how the method used to measure the anticipated outcomes will produce rigorous evidence that the outcomes were not produced due to random chance, general economic conditions, or participant selection (see Section A.6.e, Evidence Standards, for more information);

9. Propose all important covariates that will be used in evaluation analysis, including how these measures will be operationalized, and the data used for them;

10. Explain how the methodology will measure relevant unanticipated outcomes and/or negative impacts;

11. Include a proposed logic model (theory of change) (see Section A.5.c, Evaluation Method);

12. Provide and justify the selected evaluation strategy, *i.e.*, RCT or quasi-experimental design;

13. Describe anticipated statistical and analytical methods, such as regression equations to be used, power calculations, and minimal detectable impacts for each proposed outcome;

14. Include the anticipated customized randomization plan if applicable;

15. State whether the design is likely to generate evidence that can support causal conclusions, as described in Section A.6.e, Evidence Standards;

16. Describe anticipated challenges, *e.g.*, attrition, failed randomization, oversubscription and plans to mitigate them; and

17. Show how the evaluation will be independent of the intervention and financing structure.

The design plan may evolve during a project's early implementation period (approximately the first 6–12 months) to ensure proper measurement of project outcomes. However, outcome targets may not change without prior approval from Treasury or the administering

federal agency. Grantees must submit the design plan to Treasury or the administering federal agency once it is finalized. The evaluation design plan will be posted on the Federal Interagency Council on Social Impact Partnerships (Interagency Council) ¹³ website.

c. Evaluation Method

The design plan must also incorporate an appropriate evaluation method. It must outline a narrative theory of change (or logic model). A compelling theory of change (1) identifies key assumptions upon which an intervention is based; (2) provides a set of testable hypotheses that measure the effect of the proposed strategy; (3) identifies expected outcomes; and (4) where available, describes interim outputs and outcomes that show the project's progress toward the same or similar interventions, or components of the intervention, in the same or similar context.

To the extent feasible and appropriate, applicants should employ experimental design methodologies that use random assignment to create treatment and control groups to measure outcomes. If such an approach is infeasible, a quasi-experimental design in which outcomes for the treatment group, or a broader target population that includes both the treatment group and those outside the treatment group, are measured relative to a comparison group may be used. Applicants that cannot implement a RCT study will not be penalized for implementing a quasi-experimental design. This quasi-experimental design must address other possible causes of the outcomes, such as selection, other policies, economic conditions, and other confounding factors. (See the definition of "quasi-experimental design" in Appendix I.C, Key Concepts and Other Terms.) If selecting this approach, the applicant must explain why an experimental design was infeasible, inappropriate, or unethical, why the proposed evaluation method is a reasonable alternative, and why the proposed approach will yield findings that support causal inference.

d. Evaluation Facilitation

Grantees are expected to participate in and manage several activities to ensure the successful independent evaluation of demonstration projects. These activities include:

- Working with the independent evaluator to facilitate the execution of the overall evaluation strategy and to ensure the intervention is performed

according to the evaluation design plan described above;

- Reporting progress and final evaluation results to Treasury and/or the relevant federal agency are delivered on schedule;
- Over the course of the performance period, working with the independent evaluator to ensure that project randomization procedures and other evaluation processes are adhered to;
- Working with the independent evaluator to modify evaluation plans, as appropriate; and
- Participating in technical assistance initiatives that Treasury, federal agencies, or experts may provide to ensure evaluation quality and consistency across projects.

e. Evidence Standards

Independent Evaluation: The evaluation used to determine whether a State or local government will receive outcome payments under SIPRA shall use experimental designs using random assignment or other reliable evidence-based research methodologies, as certified by the Interagency Council, that allow for the strongest possible causal inferences when random assignment is not feasible.¹⁴ The project's independent evaluation must be designed to assess the strength of the causal evidence, *i.e.*, the degree to which the research establishes the causal impact of the intervention on the outcomes of interest not due to other factors.¹⁵

Evidence Base for Selecting a Project Model: Pay for results projects must be informed by designs that support causal conclusions (*i.e.*, studies with high internal validity) and that, in total, include enough of the range of participants and settings to support scaling up to the state, regional, or national level (*i.e.*, studies with high external validity). These include well-designed and well-implemented experimental studies or well-designed and well-implemented quasi-experimental studies that support the effectiveness of the practice, strategy, or program; and large, well-designed and well-implemented randomized controlled, multi-site trials that support the effectiveness of the practice, strategy, or program.

¹⁴ See 42 U.S.C. 1397n-4(c).

¹⁵ More information on evidence standards in the context of Federal program evaluations can be found at <https://www2.ed.gov/about/offices/list/oese/oss/technicalassistance/edgarrevisionsfactsheet101617.pdf>. General explanation of Federal guidelines regarding evaluation and evidence can be found in OMB Circular No. A-11 (2018), Part 6, Section 200.22, "Evaluation" and "Evidence" entries: <https://www.whitehouse.gov/wp-content/uploads/2018/06/a11.pdf>.

f. Contract With Independent Evaluator

Because the evaluation findings provide the basis for pay for results payments to the grantee, the contract each applicant enters into with an independent evaluator should require an agreed-upon evaluation design and methodology, observed outcome measure(s), and findings regarding outcome targets.

The contract with the independent evaluator should address the following:

- Plan to obtain relevant datasets from various sources, for example, local agencies, state agencies, or other federal agencies, including the responsibilities of the grantee and evaluator in accomplishing this task;
- Design and coding of a management information system, as needed, that is tailored for research or evaluation, to track participants and obtain individual-level data;
- Collection or assessment of individual-level data. The independent evaluator must work directly with the applicant and other organizations to enter into one or more agreements for the access and use of the data. These agreements should include assuring data quality and adherence to all federal and state data privacy statutes and policies and data security standards;
- Institutional Review Board (IRB) approval to ensure the protection of human subjects, to the extent applicable; and
- Submission of progress reports to Treasury, the Interagency Council, and the head of the relevant agency in accordance with the reporting requirements described in Section F.5b, Evaluation Progress Reports, and Section F.5.c, Evaluation Final Reports.

B. Federal Award Information

1. Type of Federal Award

Treasury expects to award up to \$66,290,000 in grants under this NOFA. Treasury anticipates making between five and fifteen grants for social impact partnership demonstration projects under this NOFA. The total amount awarded under this NOFA will be determined based on the strength of the applications received, the number of successful applications for projects for the direct benefit of children, and other programmatic considerations. Treasury reserves the right to make no awards or to make awards for amounts less than the amounts requested by applicants. As noted above, for projects funded under this NOFA, the federal government, under separate agreements with grantees, will also make available up to 15 percent of the project award amount for the cost of an independent evaluator.

¹³ See 42 U.S.C. 1397n-10(3)(f).

These agreements to pay for evaluations will provide for payment regardless of outcomes, but the agreements will limit payments to evaluation work performed.

2. Project Period

The period of performance for demonstration project awards may not exceed seven and a half years, which includes an intervention period of up to seven years followed by up to six months for final measurement, analysis, evaluation, submission of the independent evaluator's final report, and submission of payment requests to the federal government.¹⁶ Applicants should carefully construct their project timeline to allow sufficient time for all required activities. Applicants must specify the intervention period and explain the basis for specifying such period. Requests to extend the period of performance beyond seven and a half years will not be considered.

C. Eligibility Information

1. Eligible Applicants

Only States or local governments are eligible applicants; applications from any other entities will not be reviewed. SIPPPRA defines the term "State" to mean each State of the United States, the District of Columbia, each commonwealth, territory, or possession of the United States, and each federally recognized Indian tribe.¹⁷ For purposes of this NOFA, the term "State" shall, consistent with the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance) at 2 CFR part 200, include any of a State's

¹⁶ SIPPPRA provides that the period of performance under the award agreements may not exceed 10 years. See 42 U.S.C. 1397n-2(c)(1)(C). Treasury will strive to maximize use of the amounts Congress appropriated to make awards and outcome payments. To help achieve this goal, Treasury decided on a seven and a half year maximum period of performance to provide sufficient flexibility for Treasury to issue an additional NOFA for SIPPPRA demonstration projects with a similar period of performance. In order to make an additional round of awards and any outcome payments associated with such awards, Treasury determined that the period of performance for the first round of awards should not exceed seven and a half years. To elaborate, SIPPPRA appropriates funds that are available for ten years to make awards. See 42 U.S.C. 1397n-9 and 1397n-13. Federal law generally provides that disbursements of funds awarded within the SIPPPRA 10 year window (e.g., outcome payments) must occur within five years after that ten year window closes. See 31 U.S.C. 1552(a). If grantees receiving awards under this NOFA do not receive outcome payments for the full amount of their awards after the seven year and a half year performance period, the difference between the award amounts and the outcome payments made will be available to make awards under the additional SIPPPRA demonstration project NOFA.

¹⁷ See 42 U.S.C. 1397n-12(6).

agencies or instrumentalities, and the terms "local government" and "federally recognized Indian tribe" shall have the meanings given in the Uniform Guidance and set forth in Appendix I.1, Applicants.¹⁸

2. Cost Sharing or Matching

Cost sharing or matching funds, as defined in the Uniform Guidance,¹⁹ are not required, and the financial contributions from any investors for project implementation are not characterized as cost sharing or matching funds.

3. Other Eligibility Criteria

The identified social problem(s) or other social benefits to be addressed by the intervention must relate to one of the outcomes identified in SIPPPRA and listed in Section A.3, Qualifying Outcomes.

D. Application and Submission Information

1. How To Obtain an Application Package

This NOFA, found at www.Grants.gov and www.Treasury.gov/SIPPPRA, contains all of the information and links to forms needed to apply for grant funding. An application package may be obtained from Grants.gov by using this NOFA's CFDA number: 21.017 or by calling the SIPPPRA Coordinator at (202) 622-0262. Information on how to apply for grants can be found at <https://www.Grants.gov/web/grants/applicants/apply-for-grants.html>.

2. Content and Form of Application Submission

a. Notice of Intent To Apply

Treasury strongly encourages State and local governments interested in applying to submit to Treasury a Notice of Intent to Apply to the SIPPPRA Program Office. Obtaining advance information about the potential number of applications, as well as the general structure of the proposed intervention projects and evaluation plans, prior to the application deadline will assist Treasury in developing a more efficient application review process. A Notice of Intent to Apply should be submitted via email to SIPPPRA@treasury.gov on or prior to April 8, 2019. Please use "Intent to Apply" in the email subject line and include the following information:

1. The applicant's name and address;
2. A general overview of the intervention, including the target population and social problem the

project will address, anticipated outcome(s) of the project, and a brief summary of the evaluation design (including, where applicable, federal data sets to which the project partners and/or evaluator anticipate needing to access, and the plan to gain access to that data);

3. Any preliminary information identifying the project partners;

4. The intervention period (not to exceed seven years); and

5. Total anticipated funding and total anticipated budget for the proposed project.

An applicant that does not submit a Notice of Intent to Apply may still apply for a project grant, and an application may differ from what the applicant included in its Notice of Intent to Apply.

b. Application for Project Award

Applications submitted in response to this NOFA must consist of the following:

1. SF-424, Application for Federal Assistance;

2. SF-424A, Budget Information for Non-Construction Programs (if applicable);

3. SF-424C, Budget Information for Construction Programs (if applicable);

4. Project Narrative, which must include an executive summary that outlines key information and provides a brief description of the applicant's proposal. The project narrative must include the following:

○ The outcome goals of the project, formulated as discussed in Section A.4.f, and rigorous evidence demonstrating that the intervention can be expected to produce the desired outcomes;²⁰

○ The project timeline, including the project intervention period;²¹

○ A description of each intervention in the project and anticipated outcomes of the intervention;²²

○ A work plan for delivering the intervention through a social impact partnership model, including the proposed payment terms (e.g., the terms of any tiered payment scheme proposed by the applicant) and performance thresholds (i.e., the outcome target or, in the case of a tiered payment scheme, range of targets);²³

○ The target population that will be served by the project and the criteria used to determine the eligibility of an individual for the project, including how the target population will be

²⁰ See 42 U.S.C. 1397n-1(c)(1), (3).

²¹ See 42 U.S.C. 1397n-1(c)(15), (17).

²² See 42 U.S.C. 1397n-1(c)(2).

²³ See 42 U.S.C. 1397n-1(c)(9), (15).

¹⁸ See 2 CFR 200.54, 200.64.

¹⁹ See 2 CFR 200.29.

identified, how individuals will be referred to the project, how they will be enrolled in it, and the extent to which affected stakeholders will be engaged in the development and implementation of the project;²⁴

○ A summary of the unmet need in the area where the intervention will be delivered or among the target population who will receive the intervention²⁵ and the expected social benefits to participants who receive the intervention and others who may be impacted;²⁶

○ The detailed roles and responsibilities of each entity involved in the project, including any State or local government entity, intermediary, service provider, independent evaluator, investor, or other stakeholder;²⁷

○ A description of whether and how the applicant and service providers plan to sustain the intervention, if it is timely and appropriate to do so, to ensure that successful interventions continue to operate after the period of the social impact partnership;²⁸ and

○ Whether and how the project is for the direct benefit of children.²⁹

5. Project Narrative Attachments;

6. SF–LLL, Disclosure of Lobbying Activities;

7. *Grant.gov* Lobbying Form;

8. SF–424B, Assurance for Non-Construction Programs (if applicable);

9. SF–424D, Assurance for Construction Programs (if applicable);

The following items are required to be submitted as attachments to the project narrative:

• *Project budget*: Provide a narrative for the budget, including amounts expected to be expended by partners.³⁰

• *Partnership agreements*: Provide a partnership agreement between the applicant and all project partners. The partnership agreement must either be signed or, if submitted in draft form, must be accompanied by signed letters of intent to enter into such an agreement should the application be successful. Refer to Section A.4.d, Partnership

Agreements for what must be included in partnership agreements.

• *Partner qualifications*: Describe the expertise of each service provider that will administer the intervention, including a summary of the experience of the service provider in delivering the proposed intervention or a similar intervention, or demonstrating that the service provider has the expertise necessary to deliver the proposed intervention.³¹ This description should include a discussion of the capacity of the service provider to deliver the intervention to the number of participants the State or local government proposes to serve in the project.³² In addition, to the extent the applicant intends to use investors and has not already identified and received commitments from them, the application should discuss the experience of the State or local government, intermediary, if any, or service provider in raising private and philanthropic capital to fund social service investments.³³ With respect to any intermediary specifically, the application should discuss the intermediary's mission and goals; its experience and capacity for providing or facilitating the provision of the type of intervention proposed; information on whether the intermediary is already working with service providers that provide this intervention or an explanation of the capacity of the intermediary to begin working with service providers to provide the intervention; its experience working in a collaborative environment across government and nongovernmental entities to implement evidence-based programs; its previous experience collaborating with public or private entities to implement evidence-based programs; its ability to raise or provide funding to cover operating costs, as applicable; its capacity and infrastructure to track outcomes and measure results, including its capacity to track and analyze program performance and assess program impact; its experience with performance-based awards or performance-based contracting and achieving milestones and targets; and an explanation of how the intermediary would monitor program success, including a description of the interim benchmarks and outcome measures.³⁴

• *Independent evaluator qualifications*: Provide a summary explaining the independence of the

evaluator from the other entities involved in the project and the evaluator's experience in conducting rigorous evaluations of program effectiveness including, where available, well-implemented RCTs on the intervention or similar interventions.³⁵ Applicants should address the following qualifications of the evaluator:

• Experience working with the datasets the project expects to use;

• Prior work in conducting implementation and causal impact analyses and how their past methodologies and evaluation design experience will be used in the proposed project;

• Qualifications of the individuals designing and overseeing the evaluation and ensuring its quality, including their education or training and type and years of experience;

• Experience in managing similar evaluation protocols (*e.g.*, this type of sampling, data collection, analysis); and

• Experience dealing with unforeseen data or implementation issues in other program evaluations. Provide specific examples and experiences dealing with unforeseen data or implementation issues.

• *Evaluation design plan*: Provide an evaluation design³⁶ plan as described in Section A.5.b, Evaluation Design Plan.

• *Independent evaluator contract*. Provide a copy of the contract to be entered into between the State or local government and the independent evaluator as described in Section A.6.f, Contract with Independent Evaluator.

• *Outcome valuation*: Provide an attachment supporting the outcome valuation, as described in Section A.5.b, Outcome Valuation, and a discussion of project savings not otherwise incorporated into the outcome valuation, including projected federal, State, and local government savings and other savings, including an estimate of the savings to the federal government, on a program-by-program basis and in the aggregate, if the project is implemented and the outcomes are achieved as a result of the intervention and, if savings resulting from the successful completion of the project are estimated to accrue to the State or local government, the likelihood of the State or local government to realize those savings.³⁷ Applicants must provide the estimated total value and savings, estimated value and savings per project participant, and estimated value and

²⁴ See 42 U.S.C. 1397n–1(c)(4), (c)(18).

²⁵ See 42 U.S.C. 1397n–1(c)(14).

²⁶ See 42 U.S.C. 1397n–1(c)(5).

²⁷ See 42 U.S.C. 1397n–1(c)(12).

²⁸ See 42 U.S.C. 1397n–1(c)(24). An applicant may discuss its commitment to scalability and building capacity or plans to maintain project benefits and/or continue the intervention beyond the period of performance in the event the intervention successfully addresses the needs of the target population. An applicant may include plans to make adaptations within its environment to strengthen or expand its proposed intervention beyond the period of performance.

²⁹ See 42 U.S.C. 1397n–2(f).

³⁰ See 42 U.S.C. 1397n–1(c)(16). The budget must include any projected federal, State, and local government costs and other costs to conduct the project. See 42 U.S.C. 1397n–1(c)(6).

³¹ See 42 U.S.C. 1397n–1(c)(10), (13).

³² See 42 U.S.C. 1397n–1(c)(23).

³³ See 42 U.S.C. 1397n–1(c)(11).

³⁴ See 42 U.S.C. 1397n–1(d).

³⁵ See 42 U.S.C. 1397n–1(c)(22).

³⁶ See 42 U.S.C. 1397n–1(c)(19)–(21).

³⁷ See 42 U.S.C. 1397n–1(c)(7), (8). A tool for these calculations will be made available on Treasury's SIPPPA website.

savings per dollar spent on the intervention, as well as the methodology used by the applicant in arriving at such estimates.

- *Legal compliance:* If an applicant proposes a project including a construction component, the applicant must identify the State and federal environmental laws, regulations, and policies that will apply to the project, and the environmental documents required under State and federal laws. If an applicant proposes a project including a transportation component, the applicant must identify applicable federal, State, and local laws relating to that component, and any transportation-related permitting and licensing documents required under federal, State and local laws. The applicant must identify laws applying to the population being served and demonstrate that the project will be in compliance with those laws. The applicant must also comply with applicable federal, State, and local privacy laws. The applicant must also identify any approved waivers of any existing laws or regulations, including but not limited to environmental or transportation laws or regulations, required by the intervention design; if waivers are pending, the applicant must include documentation that it has sought the waiver, that it is under consideration, and when approval is expected to be received. Failure to obtain a necessary waiver may be grounds for termination of a grant.

An application may contain additional supporting documentation as attachments such as an existing feasibility study.

3. Other

a. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System of Award Management (SAM)

Applications will be identified by the DUNS number of the State or local government lead applicant. A DUNS number is a unique, nine-digit sequence recognized as the universal standard for identifying and keeping track of over 70 million entities worldwide. Sub-awards may be made only to entities that have DUNS numbers. Information on how to obtain a DUNS number may be obtained from Dun and Bradstreet, Inc. at <http://fedgov.dnb.com/webform> or by calling 866-705-5711. Applicants should obtain this DUNS number immediately to ensure all registration steps are complete prior to submitting an application. The DUNS number should be entered in the block with the applicant's name and address on the cover page of the application, block 8c on the Form SF 424, Application for

Federal Assistance. The name and address in the application should be exactly as given for the DUNS number. After obtaining a DUNS number, applicants must also register with the SAM, a federal governmentwide portal used for acquisition and federal assistance processes, and maintain an active SAM registration until the application process is complete and, if a grant is awarded, throughout the life of the award. SAM registration must be renewed annually. Treasury suggests finalizing a new registration or renewing an existing one at least one month before the application deadline to allow time to resolve any issues that may arise. Applicants must use their SAM-registered legal name and address on all grant applications to Treasury. Treasury will not make an award to an applicant if the applicant has not complied with all applicable DUNS and SAM requirements.³⁸

b. Privileged or Confidential Information

SIPPRA establishes a Commission on Social Impact Partnerships (Commission) whose principal obligation is to make recommendations to Treasury regarding the funding of SIPPRA demonstration project and feasibility studies.³⁹ The Commission is subject to the provisions of the Federal Advisory Committee Act (FACA), which generally requires that documents made available to the Commission be made available for public inspection and copying.⁴⁰ Treasury expects to provide to the Commission all complete applications received under this NOFA from eligible applicants and expects to make these applications available for public inspection and copying. However, FACA also provides that trade secrets and commercial or financial information that is privileged or confidential under the Freedom of Information Act (confidential business information) need not be made publicly available.⁴¹ In order to comply with FACA's public disclosure requirements while protecting confidential business information in accordance with FACA, each applicant must propose redactions of confidential business information. An applicant may omit pages for which it does not propose any redactions. Proposed redactions must be highlighted in a way that leaves the material proposed to be redacted visible

to Treasury staff. Treasury will review the redactions proposed by each applicant.

4. Submission Date, Times, Process and Addresses

Applications must be submitted between 9:00 a.m. Eastern Time on April 22, 2019, March 28, 2019 and 4:00 p.m. Eastern Time on May 22, 2019. Applications must be submitted electronically through *Grants.gov*. Mail, email, telegram, or facsimile (FAX) submissions will not be accepted. Registration for *Grants.gov* is a multi-step process that may take several weeks to complete before an application may be submitted. *Grants.gov* scheduled maintenance and outage times are announced on the *Grants.gov* website, <http://www.Grants.gov>. The deadline will not be extended due to scheduled maintenance or outages. Applicants take a significant risk by waiting to the last day to submit by *Grants.gov*.

General information for registering and submitting applications through *Grants.gov* can be found at <https://www.Grants.gov/web/grants/applicants.html> along with specific instructions for the forms and attachments required for submission. Applicants encountering a problem with *Grants.gov* may call the *Grants.gov* Contact Center at 1-800-518-4726 or 606-545-5035 to speak to a Customer Support Representative, or email support@Grants.gov. The Contact Center is open 24 hours a day, seven days a week, other than on federal holidays, when it is closed. All required documents comprising the application must be included at the time the application is submitted as set forth in Section D.2, Content and Form of Application.

Applications may be withdrawn by providing written notice to SIPPRA@Treasury.gov at any time before an award is made.

5. Intergovernmental Review

This funding opportunity is subject to Executive Order 12372, "Intergovernmental Review of Federal Programs," as amended by Executive Order 12416. Some States require that applicants contact their State's Single Point of Contact (SPOC) to comply with the State's SPOC process established pursuant to Executive Order 12372. Names and addresses of the SPOCs are listed on the Office of Management and Budget's homepage at <https://www.whitehouse.gov/wp-content/uploads/2017/11/SPOC-Feb.-2018.pdf>. Applications from federally-recognized Indian tribes are not subject to intergovernmental review.

³⁸ For more information about SAM, see the information provided by the General Services Administration at <https://www.sam.gov/SAM/pages/public/generalInfo/aboutSAM.jsf>.

³⁹ See 42 U.S.C. 1397n-6.

⁴⁰ See 5 U.S.C. App. 2 10(b).

⁴¹ See *id.*; 5 U.S.C. 552(b)(4).

6. Funding Restrictions

Grants will only be awarded to those entities and for those projects that are eligible as described in Section C, Eligibility Information. As discussed above in Section A.2, Types of Funding and Funding Availability, SIPPPRA provides that not less than 50 percent of all federal payments made to carry out social impact partnership project agreements shall be used for initiatives that directly benefit children.

E. Application Review Information

1. Review and Selection Process

Review of applications for grants under this NOFA will be conducted through the following five phases.

Phase 1: Completeness and Eligibility Review

In the first review phase, Treasury will review all applications to determine eligibility and completeness, which will consist of a non-substantive review to determine whether the applicant is a State or local government; whether the proposed project qualifies as an eligible project as set forth in

Section A.3, Qualifying Outcomes; and whether each of the application content requirements set forth in Section D.2, Content and Form of Application, has been satisfied. An application received from an ineligible entity or for an ineligible project will be rejected. Applicants are required to establish that the proposed project is an eligible project. Incomplete applications may, at Treasury’s discretion, receive further consideration. Treasury expects to afford applicants a reasonable opportunity to cure such incompleteness.

Phase 2: Subject Matter Expert Panel Review

Treasury will assign complete applications submitted by eligible applicants to one or more panels of subject matter experts who will be selected based on their knowledge of the social benefit(s) or problem(s), technical expertise in the type of intervention, experience working with the target population that is the subject of the application, or other considerations. Review panelists may be selected from federal agencies or from the private

sector, or both. Reviewers will be screened for conflicts of interest.

The panel assigned to an application will score that application in accordance with the criteria set forth in the table below, which reflects the considerations that Treasury, in consultation with the Interagency Council and the head of the relevant federal agency, is required by SIPPPRA to consider when granting awards⁴² and each of the application content requirements under SIPPPRA.⁴³ The total and component scores will serve as a reference in the further phases of review discussed below, and awards may be made out of rank order. The panel scores will not be binding with respect to these further phases of review; furthermore, Treasury may reject applications that show significant deficiencies with respect to any one component that is critical to the success of the project under the pay for results model, e.g., an application that does not identify an evaluator that is independent from the other project participants, regardless of the applicant’s total score.

Value of and Savings from the Project		15 points.
—Value to the federal government	10 points.	
—Savings to the State or local government	5 points.	
Likelihood of Achieving Outcomes		50 points.
—Evidence demonstrating intervention can be expected to achieve desired outcome	15 points.	
—Project budget, work plan, timeline, and partnership agreement	20 points.	
—Project partners	15 points.	
Quality of Evaluation		30 points.
—Evaluation design and metrics	20 points.	
—Evaluator independence and experience	10 points.	
Capacity and Commitment to Sustain the Intervention		5 points.
Total		100 points.

Value of and Savings From the Project

SIPPPRA requires Treasury to take into consideration the value to the federal government of the outcomes expected to be achieved if the outcomes specified in the grant agreement are achieved as a result of the intervention.⁴⁴ SIPPPRA also requires Treasury to take into consideration both the savings to the federal government and the savings to the State and local governments.⁴⁵

The outcome valuation is the public benefit resulting from achieving the outcome target(s), including public sector savings, defined as reduction in outlay costs, and changes in federal tax receipts. The federal payment to the State or local government for each specified outcome achieved as a result of the intervention must be less than or equal to the value of the outcome to the federal government over a period not exceeding the intervention period.⁴⁶

Value calculated for the purpose of this NOFA is discussed in Section A.4.f.ii, Outcome Valuation. The term “savings” refers to reduced outlays, whether by the federal or State or local government, as applicable, as a result of the project. Interventions may also result in savings to the State or local government, which will be taken into consideration when deciding which projects to fund.⁴⁷ As noted above, however, the federal payment to the

⁴² See 42 U.S.C. 1397n-2(b).

⁴³ See 42 U.S.C. 1397n-1(c), 1397n-1(d).

⁴⁴ See 42 U.S.C. 1397n-2(b)(2).

⁴⁵ See 42 U.S.C. 1397n-2(b)(4), (5).

⁴⁶ See 42 U.S.C. 1397n-2(c)(1)(B).

⁴⁷ See 42 U.S.C. 1397n-2(b)(5).

State or local government for each specified outcome achieved as a result of the intervention will be limited to the value of the outcome to the federal government, which is the sum of (1) savings to the federal government and (2) increased federal revenues as a result of the project, over a period not exceeding the intervention period.

The panels will review the applicant's identified target population, outcome goals and proposed intervention(s) and description of the unmet need in the area where the intervention will be delivered or among the target population that will receive the intervention.⁴⁸ The required description of expected social benefits to participants who receive the intervention and others who may be impacted will also be relevant to the extent they impact the value of and savings from the project.⁴⁹ In addition, savings to the federal government and State and local governments are specifically addressed by the requirements for applicants to provide projected federal, State, and local government savings and other savings, including an estimate of the savings to the federal government, on a program-by-program basis and in the aggregate, if the project is implemented and the outcomes are achieved as a result of the intervention,⁵⁰ and, if savings resulting from the successful completion of the project are estimated to accrue to the State or local government, the likelihood of the State or local government to realize those savings.⁵¹

In evaluating applications with respect to both value and savings, the panels will take into consideration the estimated total value and savings, estimated value and savings per project participant, and estimated value and savings per dollar spent on the intervention, as well as the methodology used by the applicant in arriving at such estimates.

Likelihood of Achieving Outcomes

SIPPRAs require Treasury to take into consideration the likelihood, based on evidence provided in the application and other evidence, that the State or local government in collaboration with the intermediary and the service providers will achieve the specified outcomes.⁵² Projects showing a greater likelihood of success will receive more points from the panels.

Evidence Demonstrating Intervention Can Be Expected To Achieve Desired Outcomes

In connection with this consideration, panels will assess applicants' compliance with the requirement to provide rigorous experimental evaluations or quasi-experimental studies demonstrating that the intervention can be expected to produce the desired outcomes.⁵³ More points will be given for applications providing greater evidence in support of the intervention and its specified outcomes; in particular, points will be awarded for evidence based on previous interventions or interventions similar to the proposed intervention that were shown to produce the desired outcomes as a direct result of the intervention and not as a result of other factors.

Project Budget, Work Plan, Timeline, and Partnership Agreement

The likelihood of success is also determined by whether the particular project is designed, structured, and implemented in a way that will foster success. To this end, the panels will assess the thoroughness and comprehensiveness of the applicant's work plan for delivering the intervention, including the proposed payment terms (*e.g.*, the terms of any tiered payment scheme proposed by the applicant), and the payment schedule (*i.e.*, the intervention period), and performance thresholds (*i.e.*, the outcome target or, in the case of a tiered payment scheme, range of targets).⁵⁴

The panels will also assess the applicant's project budget, including projected costs, and the project timeline.⁵⁵ The panels will assess the strength of the partnership agreement to the extent not covered under other components of the panel's scoring criteria. Applications will be assessed with respect to both the thoroughness of the budget, timeline, and partnership agreement and the extent to which the intervention is achievable under the budget, work plan, timeline, and partnership agreement, particularly the service delivery plan included in the partnership agreement. To the extent the applicant intends to use investors and has not already identified and received commitments from them, the panel will consider the experience of the State or local government, intermediary, or service provider in raising private and

philanthropic capital to fund social service investments.⁵⁶

Panels will also review the criteria used to determine the eligibility of an individual for the project, including how the target population will be identified, how individuals will be referred to the project, and how they will be enrolled in it.⁵⁷ Applications will be assessed based on the soundness of the methodology for identifying the target population and the thoroughness of the applicant's plan for referring and enrolling individuals, including assurances that the process avoids targeting easier-to-serve individuals from the target population for enrollment. The panel will also consider whether, to the extent applicable, the applicant has demonstrated that members of the target population are not being unfairly discriminated against in the selection, referral, and enrollment process. (See Section F.2.c, Non-discrimination laws and regulations.) Panelists will also review the extent to which the target population and related community will be engaged in the development and implementation of the project.

Project Partners

In recognition that the likelihood of success is also determined by the capabilities of the project partners, the panels will assess the assigned responsibilities and the qualifications of the partners. This will include an assessment of the applicant's description of the roles and responsibilities of each entity involved in the project, including, to the extent applicable, any State or local government entity, intermediary, service provider, investor, or other stakeholder.⁵⁸ The panel will also assess the relevance and depth of expertise of each service provider and capacity of each service provider to deliver the intervention, as described by the applicant.⁵⁹ Likewise, the panel will review the relevance and depth of experience of any project intermediary and the capacity of the intermediary to fill the roles assigned to it.⁶⁰

Quality of Evaluation

SIPPRAs require Treasury to consider the expected quality of the evaluation that would be conducted with respect to the agreement.⁶¹ The panels will assess the project's evaluation design;⁶² the

⁴⁸ See 42 U.S.C. 1397n-1(c)(1), (2), (4), (14).

⁴⁹ See 42 U.S.C. 1397n-1(c)(5).

⁵⁰ See 42 U.S.C. 1397n-1(c)(7).

⁵¹ See 42 U.S.C. 1397n-1(c)(8).

⁵² See 42 U.S.C. 1397n-2(b)(3).

⁵³ See 42 U.S.C. 1397n-1(c)(3), 1397n-2(c)(1)(D).

⁵⁴ See 42 U.S.C. 1397n-1(c)(9), (15). As to 42 U.S.C. 1397n-1(c)(15), the methodology used to calculate outcome payments is discussed under "Quality of the Evaluation" below.

⁵⁵ See 42 U.S.C. 1397n-1(c)(6), (16), (17).

⁵⁶ See 42 U.S.C. 1397n-1(c)(11).

⁵⁷ See 42 U.S.C. 1397n-1(c)(18).

⁵⁸ See 42 U.S.C. 1397n-1(c)(12), (d)(8).

⁵⁹ See 42 U.S.C. 1397n-1(c)(10), (13), (23).

⁶⁰ See 42 U.S.C. 1397n-1(d).

⁶¹ See 42 U.S.C. 1397n-2(b)(6).

⁶² See 42 U.S.C. 1397n-1(c)(19).

metrics that will be collected and analyzed in the evaluation to determine whether the outcomes have been achieved as a result of the intervention and how the metrics will be measured;⁶³ and the applicant's explanation of how the metrics used in the evaluation are independent, objective indicators of impact and are not subject to manipulation by the service provider, intermediary, or investors, if any.⁶⁴ Additionally, the panel will assess the independence of the evaluator from the other entities involved in the project and the evaluator's experience in conducting rigorous evaluations of program effectiveness, including, where available, well-implemented RCTs on the intervention or similar interventions.⁶⁵ As discussed above, the independence of the evaluator is crucial to the pay-for-results financing model.

Capacity and Commitment To Sustain the Intervention

Finally, SIPPR requires Treasury to take into consideration the capacity and commitment of the State or local government to sustain the intervention, if appropriate and timely and if the intervention is successful, beyond the period of the social impact partnership.⁶⁶ Panels will consider applicants' submissions with respect to State or local government and service providers' plans to sustain the intervention.⁶⁷ Although the primary focus with respect to an application will be on the project period, with respect to this consideration, panels will provide additional points to applications that demonstrate a commitment from the State or local government and service providers and the availability of sufficient funding to extend the project, if appropriate, beyond the project period.⁶⁸

Phase 3: Consistency Review and SIPPR Commission Recommendation

Following the panel review, Treasury will review application scores for consistency among subject matter experts on each panel and across panels and rank the applications. The SIPPR

Commission will then review applications and make award recommendations to Treasury.

Phase 4: Interagency Council Certification and Treasury Determination

The Interagency Council, which is required to certify that applications contain rigorous, independent data and reliable, evidence-based research methodologies before Treasury makes its award decision,⁶⁹ will determine which applications warrant certification.

Treasury, in consultation with the Interagency Council and the head of any federal agency administering a similar intervention or serving a population similar to that served by the project, will review the applications taking into account the statutory considerations referenced above as well as the recommendations made by the SIPPR Commission and the Interagency Council certification (or absence thereof). Depending on the number of meritorious applications, Treasury may also take into consideration the extent to which proposed projects would foster innovation in social policy, yield a diversity of target populations and grantees, and benefit economically distressed rural and urban areas, including qualified opportunity zones, as described in Executive Orders 13790 and 13853.

Finally, as noted above, SIPPR requires that "[n]ot less than 50 percent of all Federal payments made to carry out agreements under this section shall be used for initiatives that directly benefit children."⁷⁰ As discussed above, to give effect to this statutory provision, Treasury will allocate a minimum of 50 percent of the funds available under this NOFA to projects designed to directly benefit children. This means that Treasury will award no more than \$33,145,000 under this NOFA for projects that do not directly benefit children.

Phase 5: Review of Federal Awardee Performance and Integrity Information System Information Data and Risk Evaluation

As required by the Uniform Guidance, Treasury will review and consider any information about an applicant that is in the Federal Awardee Performance and Integrity Information System (FAPIIS) before making any award in excess of the simplified acquisition threshold (currently \$250,000) over the period of performance. Each applicant 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. Treasury will consider any comments by the applicant, in addition to other information in FAPIIS 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 the Uniform Guidance.⁷¹

Further, as required by Appendix XII of the Uniform Guidance, non-federal entities (NFEs) are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, or affirm that there is no new information to provide.⁷² This applies to NFEs for which the total value of active grants, cooperative agreements, and procurement contracts received from all federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of an award or project. This means that Treasury may reject an application based on the information contained in FAPIIS even if the applicant otherwise scores highly under the 100 point scale.

Treasury will comply with the requirements of 31 CFR part 19, Government wide Debarment and Suspension (Non-procurement). Additionally, as part of its risk evaluation, Treasury may impose special conditions on an award that correspond to the degree of risk identified in Treasury's review of the application. Criteria to be evaluated include: (1) Financial stability; (2) quality of management systems and ability to meet the management standards prescribed in the Uniform Guidance; (3) the applicant's record in managing awards, cooperative agreements, or procurement awards, if it is a prior recipient of such federal awards, including timeliness of compliance with applicable reporting requirements and, if applicable, the extent to which any previously awarded amounts will be expended prior to future awards; (4) reports and findings from audits performed under Subpart F, Audit Requirements of the Uniform Guidance, or the reports and findings of any other available audits and monitoring reports containing findings, issues of non-compliance or questioned

⁶³ See 42 U.S.C. 1397n-1(c)(20).

⁶⁴ See 42 U.S.C. 1397n-1(c)(21).

⁶⁵ See 42 U.S.C. 1397n-1(c)(22).

⁶⁶ See 42 U.S.C. 1397n-2(b)(7).

⁶⁷ See 42 U.S.C. 1397n-1(c)(24).

⁶⁸ As noted above, an applicant may discuss the commitment to scalability and building capacity or plans to maintain project benefits and/or continue the intervention beyond the project period in the event the intervention successfully addresses the needs of the target population. An applicant may include plans to make adaptations within its environment to strengthen or expand its proposed intervention beyond the period of performance.

⁶⁹ See 42 U.S.C. 1397n-5(a)(8).

⁷⁰ 42 U.S.C. 1397n-2(f).

⁷¹ See 2 CFR 200.205.

⁷² See 2 CFR part 200, appendix XII.

costs; and (5) the applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on recipients.

2. Application Clarification and Feedback

During the course of the review process and risk assessment evaluation, Treasury may ask some applicants to provide confirming or clarifying information. Treasury staff uses such information to inform funding recommendations. A request for confirmation or clarification does not guarantee a grant award. If an applicant does not respond by the deadline to a request for information, Treasury may remove its application from consideration.

Upon request, Treasury expects to provide feedback to unsuccessful applicants after grant awards have been announced.

F. Award Administration Information

1. Award Notices

Before the actual grant is awarded, Treasury may enter into negotiations with the applicant regarding program components, staffing and funding levels, and/or administrative systems in place to support grant implementation. If the negotiations do not result in a mutually acceptable submission, Treasury reserves the right to terminate the negotiations and decline to fund the award.

Treasury expects to announce the results of this competition by November 2019. Treasury will provide successful applicants with a Notice of Award (NoA) that will set forth the amount of the award and other pertinent information. The NoA is the legal document issued to notify an applicant that an award has been made. Treasury expects that the NoA will also include standard Terms and Conditions and any Special Award Conditions related to participation in the Social Impact Partnerships Demonstration program. The NoA will be sent through the U.S. Postal Service to the applicant listed on the SF-424; a copy will also be sent to the electronic mail address listed on the SF-424. The applicant's signature on the SF-424, including electronic signature via E-Authentication on <http://www.grants.gov>, constitutes a binding offer by the applicant. Note that any communication between Treasury and applicants prior to the issuance of the NoA and prior to the execution of any award agreement is not authorization to begin performance on the project.

Unsuccessful applicants will be notified of their status by letter, which will likewise be sent through the U.S. Postal Service to the applicant listed on the SF-424. Unsuccessful applicants may apply under subsequent NOFAs.

2. Administrative and National Policy Requirements

Successful applicants selected for awards must agree to comply with additional applicable legal requirements upon acceptance of an award. All grants are subject to the Office of Management and Budget's regulatory requirements for grants codified in the Uniform Guidance. Grantees and, if applicable, sub-recipients must agree as part of their award agreement to comply with all requirements under 2 CFR part 200, as applicable. Treasury does not expect that the cost principles in Subpart E of 2 CFR part 200 will be applicable, except with regard to federal funding for the independent evaluator.

a. Administrative Program Requirements

Awards under this NOFA are subject to federal laws, regulations, and policies concerning grants. Below is a non-exhaustive list of requirements with which the applicant will need to comply:

1. Lobbying Restrictions at 31 CFR part 21.
2. Government-wide Debarment and Suspension Requirements at 31 CFR part 19.
3. Government-wide Requirements for Drug-Free Workplace at 31 CFR part 20.
4. Award Term for Trafficking in Persons at 2 CFR part 175.

b. Environmental Requirements

Treasury approval of financial assistance is subject to compliance with applicable federal and State environmental requirements. As discussed under Section D.2.b, Application for Project Award, the applicant must identify the State and federal environmental laws, regulations, and policies that may apply to the project and the environmental documents that may be required under State and federal laws. As to the National Environmental Policy Act of 1969, as amended (NEPA),⁷³ specifically, project applications will be evaluated in accordance with Treasury's NEPA procedures and categorical exclusions. Grantees whose projects do not fall within Treasury's categorical exclusions will be required to assist Treasury in conducting an Environmental Analysis and an

Environmental Impact Statement for the project, as applicable.

c. Non-Discrimination Laws and Regulations

All grantees, partners, and sub-recipients, if applicable, must comply with applicable non-discrimination statutes and regulations. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000-2000d7), which prohibits discrimination on the basis of race, color of national origin, and Treasury's implementing regulations, 31 CFR part 22; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794), which prohibits discrimination on the basis of disability, and Treasury's implementing regulations, 31 CFR part 28; (d) the Individuals with Disabilities Act, as amended (20 U.S.C. 1400 *et seq.*); (e) the Age Discrimination Act of 1975, as amended (42 U.S.C. 6101-6107), which prohibits discrimination on the basis of age, and Treasury's implementing regulations, 31 CFR part 23; (f) the Drug Abuse Office and Treatment Act of 1972 (Pub. L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (g) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Pub. L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (h) Section 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290dd-3 and 290ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; and (i) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. 3601 *et seq.*), as amended, relating to nondiscrimination in the sale, rental or financing of housing.

d. Other Requirements

Grantees must comply with existing laws and regulations governing the subject area of the project and the relevant federal agency administering the project. If the intervention design requires exceptions to any such existing laws and regulations, the applicant must obtain a waiver from the governing federal, State, or local agency.

e. Transparency Act Requirements

Applicants must ensure that they have the necessary processes and systems in place to comply with the reporting requirements of the Federal Funding Accountability and

⁷³ 42 U.S.C. 4321 *et seq.*

Transparency Act of 2006 (Pub. L. 109–282, as amended by § 6202 of Pub. L. 110–252) (Transparency Act). All applicants, except for those excepted from the Transparency Act, must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements of the Transparency Act, should they receive funding. Upon award, applicants will receive detailed information on the reporting requirements of the Transparency Act, as described in 2 CFR part 170, Appendix A. No sub-award of an award made under this NOFA may be made to a sub-recipient that is subject to the terms of the Transparency Act unless that potential sub-recipient acquires and provides a DUNS number.

3. Special Program Requirements

a. Access to Records/Oversight

By accepting a project award under this NOFA, the grantee agrees to make available to Treasury, the Comptroller General, agency Inspectors General, the administering agency, or any of their authorized representatives, all data and documents that might be needed, including contracts and agreements, regardless of whether outcomes are achieved and payment is received, in the grantee's possession or available to the grantee. Grantees must also agree to provide timely and reasonable access to program operating personnel, project partners, and participants. This evaluation may make use of program management information system data, local administrative data, financial data, and program progress reports. It is critical that grantees keep this information up to date and accurate for performance measurement, evaluation, and auditing purposes. Grantees may be required to: (1) Provide access to pertinent documents; (2) host site visits; (3) facilitate interviews with grantee staff, partners and the independent evaluator; (4) attend grantee meetings; and (5) provide additional data. By accepting a project award under this NOFA, the grantee also agrees to participate in a national cross-site evaluation in the event that the federal government conducts one.

b. Evaluation Agreement

For each social impact project grant approved by Treasury, the head of the relevant federal agency, as recommended by the Interagency Council and determined by Treasury, will enter into an agreement with the grant recipient to pay for all or part of the independent evaluation for the

project up to 15 percent of the award amount.⁷⁴ Under SIPPRA, the head of the relevant federal agency may not enter into an agreement with a State or local government unless the head determines that the evaluator is independent of the other parties to the agreement and has demonstrated substantial experience in conducting rigorous evaluations of program effectiveness including, where available and appropriate, well-implemented randomized controlled trials on the intervention or similar interventions.⁷⁵

c. Federal Register Publication of Notice of Award

SIPPRA provides that not later than 30 days after entering into an agreement for an award, Treasury must publish a notice in the *Federal Register* that includes the following information about the award:

- (1) The outcome goals of the project.
- (2) The target population that will be served by the project.
- (3) A description of each intervention in the project.
- (4) The expected social benefits to participants who receive the intervention and others who may be impacted.
- (5) The detailed roles, responsibilities, and purposes of each federal, State, or local government entity, intermediary, service provider, independent evaluator, investor, if any, or other stakeholder.
- (6) The payment terms, the methodology used to calculate outcome payments, the payment schedule, and performance thresholds.
- (7) The project budget.
- (8) The project timeline.
- (9) The project eligibility criteria.
- (10) The evaluation design.
- (11) The metrics that will be used in the evaluation to determine whether the outcomes have been achieved as a result of each intervention and how these metrics will be measured.
- (12) The estimate of the savings to the federal, State, and local government, on a program-by-program basis and in the aggregate, if the agreement is entered into and implemented and the outcomes are achieved as a result of each intervention.⁷⁶

Additionally, SIPPRA requires that this information, along with progress reports and final reports relating to each project, be posted on a website established and maintained by the Interagency Council.⁷⁷

⁷⁴ See 42 U.S.C. 1397n–4(a).

⁷⁵ See 42 U.S.C. 1397n–4(b).

⁷⁶ See 42 U.S.C. 1397n–2(d).

⁷⁷ See 42 U.S.C. 1397n–10.

d. Changes to the Statement of Work

Upon grant of an award, the proposal will become the grant's statement of work. Treasury discourages any changes to the target population, outcome(s), intermediary, and independent evaluator. Under extenuating circumstances, Treasury and/or the relevant federal agency administering the grant at its sole discretion may approve revisions to the statement of work. Changes to the intervention strategy and source of up-front project funding may be made with prior written approval from Treasury or the administering federal agency. To start this process, a grantee must timely notify William Girardo, SIPPRA Coordinator, at (202) 622–0262 or SIPPRA@Treasury.gov of these changes as they occur and provide appropriate documentation to update the statement of work.

4. Intellectual Property Rights

Intellectual property rights relating to the activities of the grantee and all partners in the project, including the evaluator, intermediary, and service provider(s) are subject to 2 CFR 200.315.

5. Administrative Reporting

Grantees must agree to meet the reporting requirements as listed below or as specified in the award agreement. Administrative reports must be submitted electronically to Treasury or to the relevant federal agency, as specified in the award agreement.

a. Performance Report

(1) Projects With No Construction Component

An OMB-approved Annual Performance Report form must be submitted within 90 days of the end of each calendar year of the award period of performance. A final performance report is due 90 calendar days after the period of performance end date. Each report must summarize project activities, including the current stage of program implementation; progress towards achieving the outcome goals, including number of people served; significant milestones of the grantee, intermediary, investors, if any, and evaluator; and related results of the project. It should thoroughly document the partnership activities and decision-making structure used to implement the pay for results model. These reports will be made publicly available. Upon award, Treasury or the administering federal agency will provide detailed formal guidance about the data and other information that is required to be

collected and reported on either a regular basis or special request basis.

(2) Projects With a Construction Component

The federal government will require additional evidence of onsite technical inspections and certified percentage of completion date information on construction elements of projects but will not require performance requirements other than the Annual Performance Report required for projects with no construction component. Projects that include the acquisition and/or improvement of real property are subject to the Uniform Guidance's Property Standards.⁷⁸

b. Evaluation Progress Reports

Not later than two years after a project has been approved and biannually thereafter, the independent evaluator must submit a written report to the head of the relevant federal agency and the Interagency Council summarizing the progress that has been made in achieving each outcome specified in the award agreement.⁷⁹ Data in evaluation progress reports and final reports will be made available to all federal agencies represented on the Interagency Council, and data content requirements will be specified in the agreement between the grantee and the head of the relevant federal agency.

When a grantee's intervention has achieved one or more outcomes, pre-defined outcome target(s) have been met, and the grantee wishes to receive an outcome payment in accordance with the outcome payment structure originally proposed, the independent evaluator must submit to the head of the relevant federal agency and the Interagency Council a written report that includes the results of the evaluation conducted to determine whether an outcome payment should be made. The report must include information on the unique factors that contributed to achieving or failing to achieve the outcome in the context of the intervention, including but not limited to any major change in policy or law that may have affected the project intervention and whether or not the project was implemented with fidelity, *e.g.*, randomization of treatment and control groups; the challenges faced in attempting to achieve the outcome; and information on the improved future delivery of this or similar interventions.⁸⁰ The report must also assess the degree to which the project

was delivered as intended, including a discussion of how closely the project's theory and intended procedures aligned with actual project implementation. The report should include information related to the intervention model, including whether it has evolved and whether the intervention was delivered with fidelity to the plan; staffing; recruitment/identification and screening of participants; selection and enrollment; how the intervention was implemented; and findings.

The progress report must include an assessment by the independent evaluator of the value to the federal government as discussed and defined in Section 4.f.ii, Outcomes: Outcome Valuation. In calculating the value to the federal government of the completed outcome(s), the independent evaluator may only take into consideration changes in federal outlays and revenues that have occurred as of the completion of the outcome and not extrapolate to later points in time or assume that other outcomes will be achieved. That is, the value calculation must only take into account the value achieved as the result of the completed outcome(s).

The Interagency Council will submit these reports to Treasury and to each committee of jurisdiction in the House of Representatives and Senate within 30 days of receipt.⁸¹

c. Final Evaluation Report

Within six months of project completion, the independent evaluator must submit a final report to the head of the relevant federal agency and the Interagency Council.⁸² The report should assess the effects of the intervention and include a discussion of the findings and implications, as well as a definitive statement about whether the predetermined outcomes have been met and whether the State or local government has fulfilled each obligation of the agreement. This must include information on the unique factors that contributed to the achievement or failure to achieve outcomes, including but not limited to any major change in policy or law that may have affected the project intervention, a description of the research methods, *e.g.*, randomization of treatment and control groups, if applicable, data, sample size and characteristics, measures, and other factors, as well as findings, including impacts—for exploratory and confirmatory, short and long-term, subgroup analyses, and other findings.

The report must also assess whether, and the degree to which the project was

delivered as intended. This must include a discussion of how closely the project's theory and intended procedures aligned with actual project implementation. This portion of the report must include information related to the intervention model, including whether it has evolved and whether the intervention was delivered with fidelity; staffing; recruitment/identification and screening of participants; selection and enrollment; and how the intervention was implemented. The report must also discuss information regarding the improved future delivery of this or similar interventions.

The independent evaluator's final report for a project must include an assessment of the value to the federal government as discussed and defined in Section 4.f.ii, Outcomes: Outcome Valuation. In calculating the value to the federal government of the completed outcome(s), the independent evaluator may only take into consideration changes in federal outlays and revenues.

The Interagency Council will submit this final report to Treasury and to each committee of jurisdiction in the House of Representatives and Senate within 30 days of receipt.⁸³ This report will be made publicly available.

6. Record Retention

Applicants must follow federal guidelines on record retention, which require grantees to maintain all records pertaining to grant activities for a period of not less than three years from the time of final grant close-out.⁸⁴

G. Agency Contacts

For further information about this NOFA, please contact William Girardo, SIPPPRA Coordinator, at (202) 622-0262 or SIPPPRA@Treasury.gov. Applicants should email all technical questions to SIPPPRA@treasury.gov and must specifically reference NOFA/CFDA 21.017, and include a contact name, fax and phone number. This NOFA is also available on Treasury's SIPPPRA website at <https://www.treasury.gov/SIPPPRA> and at <http://www.Grants.gov>.

H. Other Information

Treasury has determined that this NOFA imposes new information collection requirements subject to the Paperwork Reduction Act of 1995. The information collection for the Notice of Intent to Apply, Project Narrative, Administrative Reporting, and Records Retention provisions contained in this NOFA has been approved under OMB control number 1505-0260. Other

⁷⁸ See 2 CFR 200.310-316.

⁷⁹ See 42 U.S.C. 1397n-4(d)(1)(A).

⁸⁰ See 42 U.S.C. 1397n-4(d)(1)(B).

⁸¹ See 42 U.S.C. 1397n-4(d)(2).

⁸² See 42 U.S.C. 1397n-4(e).

⁸³ See 42 U.S.C. 1397n-4(e)(2).

⁸⁴ See generally 2 CFR 200.333.

information requirements gathered via the SF-424 family of forms have already been approved under the following OMB control numbers: Information for Federal Assistance covered under 4040-0004, Budget Information for Non-Construction Programs covered under 4040-0006, Budget Information for Construction Programs covered under 4040-0008, Disclosure of Lobbying Activities covered under 4040-0013, Assurance for Non-Construction Programs covered under 4040-0007, Assurance for Construction Programs covered under 4040-0009 and Key Contacts, Project Abstract and Project/Performance Site Location covered under 4040-0010.

Appendix I. Definitions

1. Applicants

Eligible applicant. A State or local government is an eligible applicant for an award under this NOFA. See definitions of “State” and “local government” below.

Federally recognized Indian tribe means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. Chapter 33), which is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians (25 U.S.C. 450b(e)). See the annually published Bureau of Indian Affairs list of Indian Entities Recognized and Eligible to Receive Services.⁸⁵ Federally recognized Indian tribes are eligible applicants under this NOFA.

Local government means any unit of government within a state, including a: (a) County; (b) borough; (c) municipality; (d) city; (e) town; (f) township; (g) parish; (h) local public authority, including any public housing agency under the United States Housing Act of 1937; (i) special district; (j) school district; (k) intrastate district; (l) Council of governments, whether or not incorporated as a nonprofit corporation under state law; and (m) any other agency or instrumentality of a multi-, regional, or intra-state or local government.⁸⁶

State means any State of the United States, the District of Columbia, each commonwealth, territory, or possession of the United States, and each federally recognized Indian tribe (see definition above), and includes any agencies or instrumentalities thereof.⁸⁷

2. Other Key Parties

The Commission on Social Impact Partnership (SIPPRA Commission) is the nine-member advisory commission established by SIPPRA consisting of a non-federal Chair appointed by the President and eight non-federal members chosen by congressional leaders. The SIPPRA Commission will make recommendations to Treasury regarding funding of social impact partnership agreements and feasibility studies.⁸⁸

The Federal Interagency Council on Social Impact Partnerships (Interagency Council) is the eleven member Interagency Council established by SIPPRA. The Interagency Council is chaired by the Director of the Office of Management and Budget and its other members consist of representatives from the Departments of Labor, Health and Human Services, Agriculture, Justice, Housing and Urban Development, Education, Veterans Affairs, and Treasury, the Social Security Administration, and the Corporation for National Community Service. The Interagency Council has ten enumerated responsibilities.⁸⁹

The independent evaluator conducts an evaluation to determine whether the intervention achieved the outcome(s) sought and prepares evaluation progress reports and a final project report which the grantee submits to the federal government.

Investor(s) are entities that, if the State or local government is not doing so, provide the funding for the social service interventions. Investors may be not-for-profit or for-profit entities or public sector funds. They accept the risk that they will not be repaid in the event that the target outcome(s) are not achieved.

The intermediary may be selected by the applicant to coordinate the pay for results arrangement. The role of the intermediary may include (1) being responsible for achieving the negotiated outcome(s) for the target population by contracting with service delivery providers; (2) raising funds from investors (if applicable) to cover the operating costs of implementing the services or programs; (3) changing or modifying service delivery methods and providers, with concurrence of the other partners, including the independent evaluator and, if applicable, investors; and (4) if outcome target(s) are met, receiving outcome payments from the State or local government and making payments to the investors, if applicable.

It is not requisite that the partnership include an intermediary organization, and a service provider, described below, may also serve as an intermediary.

Service provider(s) deliver the intervention designed to achieve the outcomes sought in a pay for results partnership agreement. An applicant, or, where applicable, an intermediary arranges with a service provider to provide services and/or administer the interventions. Note that a service provider may be a State or local government agency.

3. Key Concepts and Other Terms

Intervention period means the period of performance minus the final six months of the period of performance that the statute stipulates is the time available for the submission of evaluation reports at the completion of all other project activities.⁹⁰ For awards under this NOFA, Treasury caps the intervention period at seven years, and the period of performance at seven and a half years.

An outcome is an impact that can be measured by one or more indicators that are specific, unambiguous, and observable during the intervention period.

Outcome measure means an assessment of what a program seeks to effect using data calculated on both target and comparison groups. Outcomes are measured using relevant program data with defined units of measurement.

Outcome target means a change in an outcome measure or a percentage improvement of the outcome measure over the duration of a project. It must be defined relative to a comparison or control group.

Quasi-experimental design means an evaluation design in which outcomes for the treatment group, or a broader target population that includes both the treatment group and those outside the treatment group, are measured relative to a comparison group. Such a design attempts to approximate an experimental design and can support causal conclusions, without random assignment. Sophisticated analytic techniques are used to control for factors that might be associated with the outcome being analyzed.

Randomized controlled trial (RCT) means a sample selection technique in which individuals are randomly assigned to a treatment or control group. The use of random assignment ensures that participants have an equal chance of being selected for either the treatment or control group. It also helps to ensure

⁸⁵ See 2 CFR 200.54.

⁸⁶ See 2 CFR 200.64.

⁸⁷ See 42 U.S.C. 1397n-12(6), 2 CFR 200.90.

⁸⁸ See 42 U.S.C. 1397n-6.

⁸⁹ See 42 U.S.C. 1397n-5.

⁹⁰ See 42 U.S.C. 1397n-4(e)(1).

that there are no significant differences between the groups. The two groups are compared to detect the difference made by the product and/or service. Such a design provides the most rigorous and widely accepted evidence of effectiveness.

Savings means a reduction in outlay costs. For example, a project yields

savings to the federal government if it results in lower federal outlays. This could be the result of dollars not spent because the intervention eliminates a need for the outlay.

Target population means the population that the social impact partnership project is intended to serve.

Dated: February 12, 2019.

Diana Furchtgott-Roth,

Acting Assistant Secretary for Economic Policy.

[FR Doc. 2019-02852 Filed 2-20-19; 8:45 am]

BILLING CODE 4810-35-P



FEDERAL REGISTER

Vol. 84

Thursday,

No. 35

February 21, 2019

Part II

The President

Notice of February 19, 2019—Continuation of the National Emergency With Respect to Cuba and Continuing To Authorize the Regulation of the Anchorage and Movement of Vessels

Notice of February 19, 2019—Continuation of the National Emergency With Respect to Libya

Title 3—

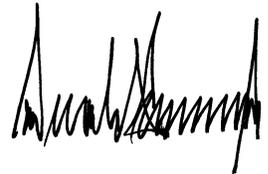
Notice of February 19, 2019

The President

Continuation of the National Emergency With Respect to Cuba and Continuing To Authorize the Regulation of the Anchorage and Movement of Vessels

On February 22, 2018, by Proclamation 9699, the national emergency with respect to Cuba declared in Proclamation 6867 of March 1, 1996, expanded by Proclamation 7757 of February 26, 2004, and modified by Proclamation 9398 of February 24, 2016, was modified and continued based on a disturbance or threatened disturbance of the international relations of the United States related to Cuba. The unauthorized entry of any United States-registered vessel into Cuban territorial waters and the situation in Cuba continue to pose an unusual and extraordinary threat to the national security and foreign policy of the United States. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)) and section 1 of title II of Public Law 65–24, ch. 30, June 15, 1917, as amended (50 U.S.C. 191), I am continuing for 1 year the national emergency declared in Proclamations 6867, 7757, 9398, and 9699.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
February 19, 2019.

Presidential Documents

Notice of February 19, 2019

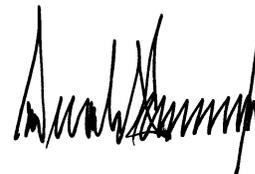
Continuation of the National Emergency With Respect to Libya

On February 25, 2011, by Executive Order 13566, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the actions of Colonel Muammar Qadhafi, his government, and close associates, which took extreme measures against the people of Libya, including by using weapons of war, mercenaries, and wanton violence against unarmed civilians. In addition, there was a serious risk that Libyan state assets would be misappropriated by Qadhafi, members of his government, members of his family, or his close associates if those assets were not protected. The foregoing circumstances, the prolonged attacks against civilians, and the increased numbers of Libyans seeking refuge in other countries caused a deterioration in the security of Libya and posed a serious risk to its stability.

The situation in Libya continues to pose an unusual and extraordinary threat to the national security and foreign policy of the United States, and measures are needed to protect against the diversion of assets or other abuses by members of Qadhafi's family, their associates, and other persons hindering Libyan national reconciliation.

For this reason, the national emergency declared on February 25, 2011, must continue in effect beyond February 25, 2019. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 13566.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
February 19, 2019.

Reader Aids

Federal Register

Vol. 84, No. 35

Thursday, February 21, 2019

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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	
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FEDERAL REGISTER PAGES AND DATE, FEBRUARY

959-1342.....	1
1343-1598.....	4
1599-2042.....	5
2043-2426.....	6
2427-2704.....	7
2705-3094.....	8
3095-3284.....	11
3285-3668.....	12
3669-3966.....	13
3967-4306.....	14
4307-4676.....	15
4677-4948.....	19
4949-5334.....	20
5335-5582.....	21

CFR PARTS AFFECTED DURING FEBRUARY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:	
9840.....	2043
9841.....	2045
9842 (See Proc. 9822).....	3665
9843.....	3965
9844.....	4949

Executive Orders:

13788 (Amended by 13858).....	2039
13858.....	2039
13859.....	3967

Administrative Orders

Memorandums:	
Memorandum of December 21, 2018.....	3957
Memorandum of December 21, 2018.....	3959
Memorandum of January 8, 2019.....	3961
Memorandum of January 15, 2019.....	3963

5 CFR

894.....	1599
1655.....	1600
Proposed Rules:	
532.....	3729

7 CFR

51.....	959
273.....	4677
300.....	2427
301.....	2427
318.....	2427
319.....	2427
330.....	2427
340.....	2427
355.....	2427
905.....	2047
932.....	4307
953.....	4681
989.....	2049
1206.....	5335
1208.....	4951
1212.....	1343
1774.....	3669
Proposed Rules:	
54.....	1641
205.....	4377
273.....	980
278.....	4739
279.....	4739
985.....	4381
1206.....	5379
1209.....	3114

9 CFR

310.....	2430
----------	------

10 CFR

2.....	2433
9.....	3095
13.....	2433
72.....	4309, 4683, 4684
430.....	2436, 5346
903.....	5347

Proposed Rules:

34.....	3116
36.....	3116
39.....	3116
50.....	2069
52.....	2069
100.....	2069
430.....	3120, 3910
431.....	1652, 3910

11 CFR

Proposed Rules:	
100.....	2070
110.....	3344
112.....	2071

12 CFR

1.....	4222
3.....	4222
5.....	4222
22.....	4953
23.....	4222
24.....	4222
32.....	4222
46.....	4222
172.....	4953
208.....	4222, 4953
211.....	4222, 4309
215.....	4222
217.....	4222
223.....	4222
225.....	4222
238.....	4309
252.....	4222
263.....	2051
303.....	2705
324.....	4222
325.....	4222
327.....	1346, 4222
337.....	1346
339.....	4953
347.....	4222
348.....	2705
390.....	4222
614.....	4953
622.....	1354
652.....	2706
700.....	1601
701.....	1601
702.....	1601
703.....	1601
704.....	1601
705.....	1601
708a.....	1601
708b.....	1601
709.....	1601

710.....1601
715.....1601
717.....1601
723.....1601
725.....1601
741.....1601
745.....1601
746.....1601
747.....1601, 2052
748.....1601
749.....1601
750.....1601
760.....1601, 4953
790.....1601
791.....1601
792.....1601
930.....5308
932.....5308
1026.....1356
1277.....5308
1411.....2437
1610.....4975

Proposed Rules:
1.....3062
3.....3062
5.....3062
6.....3062
23.....3062
24.....3062
32.....3062
34.....3062
44.....2778
46.....3345
160.....3062
192.....3062
206.....3062
208.....3062
211.....3062
215.....3062
217.....3062
223.....3062
225.....3062
238.....3062, 4002, 5014
248.....2778
251.....3062
252.....4002, 5014
303.....3062
324.....3062
327.....5380
337.....2366, 3062
347.....3062
351.....2778
362.....3062
365.....1653, 3062
390.....1653, 3062
614.....5389
1041.....4252, 4298

14 CFR
39.....2437, 2707, 2709, 2713,
2715, 3285, 3288, 3290,
3297, 4310, 4313, 4315,
4318, 4320, 4685, 4686,
4692, 4694, 4987, 5350
48.....3669
71.....961, 2718, 3095, 3097,
3098, 3101, 3673, 3674,
3676, 3677, 3679, 4991,
4993, 5352
73.....3299
95.....963
97.....2441, 2443, 2719, 2720,
3973, 3975, 3977, 3978,
4994, 4996

Proposed Rules:
13.....3614

39.....2465, 2467, 2791, 2793,
2796, 3131, 4012, 4387
71.....3349, 3730, 5014, 5016,
5017, 5019, 5392
107.....3732, 3856

15 CFR
6.....2445
902.....2725
950.....3101

16 CFR
1.....3980

Proposed Rules:
Ch. II.....3134

17 CFR
143.....3103
200.....5202
201.....4906
229.....2402
240.....2402, 4906
242.....5202

Proposed Rules:
Ch. I.....3350
9.....3350
36.....3350
37.....3350
38.....3350
39.....3350
43.....3350
75.....2778
230.....5393
232.....5393
239.....5393
240.....4614, 5393
255.....2778
270.....1286, 5393
274.....1286, 5393

18 CFR
11.....1359
250.....966
385.....966, 3982

Proposed Rules:
7.....2469
35.....993
141.....1412
385.....1412

20 CFR
30.....3026
404.....4323
408.....4323
416.....4323

Proposed Rules:
404.....1006
416.....1006

21 CFR
216.....4696
872.....4998
1308.....2448

Proposed Rules:
1305.....5395

22 CFR
Proposed Rules:
171.....1419
203.....3351

23 CFR
1270.....2731
1275.....2731

Proposed Rules:
658.....2071

25 CFR
Proposed Rules:
30.....3135

26 CFR
1.....1838, 2952

Proposed Rules:
1.....1014, 3015

27 CFR
Proposed Rules:
9.....3353

29 CFR
30.....3301
4022.....3983

Proposed Rules:
1404.....1420
4001.....2075
4204.....2075
4206.....2075
4207.....2075
4211.....2075
4219.....2075
1614.....4015

31 CFR
27.....3105

32 CFR
75.....3681
100.....968
101.....968
162.....4710
199.....4326
279.....969
807.....5353
809a.....2734
813.....5353
884.....5354

33 CFR
100.....3301
117.....1401, 2735
165.....969, 2736, 4333, 5354

Proposed Rules:
100.....4390
154.....2799
155.....2800
165.....2479
328.....2483, 4154
334.....3739

34 CFR
36.....971
668.....971

Proposed Rules:
106.....4018

37 CFR
201.....3693
202.....3693, 3698
203.....3699
385.....1918

Proposed Rules:
2.....4393
11.....4393
201.....1661

38 CFR
3.....2449, 4336
8.....2449, 4336
14.....2449, 4336
19.....2449, 4336

20.....2449, 4336
21.....2449, 4336

Proposed Rules:
4.....1678, 3354
38.....2093
39.....2093

39 CFR
20.....3107
3035.....974

Proposed Rules
3020.....1420

40 CFR
19.....2056
52.....976, 1610, 1615, 2060,
2063, 2449, 2738, 3302,
3305, 3701, 3703, 3705,
3708, 3711, 3986, 3991,
4338, 5000, 5004
60.....3108, 3985, 3986
61.....3108
62.....3712
63.....2742, 3108, 3308
70.....1615, 3108
80.....2453
122.....3324
124.....3324
125.....3324
180.....2456, 4340, 4345

Proposed Rules:
Ch. I.....3396
49.....1690
52.....1015, 1016, 1021, 1025,
1037, 1690, 2109, 2801,
3354, 3358, 3369, 3373,
3376, 3381, 3384, 3387,
3389, 3740, 3742, 3744,
4019, 4021, 4025, 4403,
4407, 4411, 4422, 4426,
5020, 5032
60.....2484, 2485
62.....1039
63.....1570, 2670
70.....5032
81.....4029, 4422, 4426
110.....2483, 4154
112.....2483, 4154
116.....2483, 4154
117.....2483, 4154
122.....2483, 4154
131.....3395
151.....4741
174.....2115
180.....1691, 2115
230.....4154
232.....2483, 4154
300.....2116, 2122, 2483, 4033,
4054
302.....2483, 4154
401.....2483, 4154

42 CFR
Proposed Rules:
493.....1536
1001.....2340

44 CFR
64.....978, 3338

45 CFR
1149.....1402
1158.....1402
1607.....1404
1611.....1408

46 CFR	5.....4742	501.....1410, 3714	563.....2804
506.....2459	25.....2126, 4742	511.....3714	1002.....1046
Proposed Rules:	32.....2132	517.....3714	1312.....1046
515.....2125	54.....2132	519.....1410	
	65.....2132	532.....3714	
47 CFR	73.....2485	536.....3714	50 CFR
0.....2753	76.....4039	543.....3714	229.....5356
1.....1618, 2460, 2461, 2753, 5008	97.....4742	546.....3714	600.....4733
5.....2753	48 CFR	552.....1410, 3714	622.....1631, 2759, 3723, 4733
25.....2462	Ch. 2.....4360	5215.....3112	635.....3724, 5358
30.....1618	204.....4362	5242.....3113	648.....1632, 2463, 2760, 3341, 4373, 5377
32.....4711	206.....4364	Proposed Rules:	665.....2767, 5378
36.....4351	211.....4366	215.....4429	679.....2067, 2068, 2723, 2776, 3342, 3726, 3727
54.....4711	212.....4362, 4368, 4370	217.....4429	680.....2723
64.....1409	215.....4364, 4368	806.....1014	697.....4733
65.....4711	234.....4364	49 CFR	Proposed Rules:
73.....2753	235.....4364	107.....3993	217.....3136
74.....2753	236.....4371	110.....3993	300.....3403, 4758
Proposed Rules:	239.....4368	Proposed Rules:	622.....4758
1.....2485, 4035	247.....4370	10.....2137, 5403	648.....5035
	252.....4362, 4368, 4370		

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 February 20, 2019

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